EXHIBIT 503

In Re:

Digitek

Phyllis A. Lambridis

January 18, 2010

Confidential – Subject to Further Confidentiality Review

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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

- - -

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION : MDL NO. 1968

(This document relates to all cases.)

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CONFIDENTIAL - SUBJECT TO FURTHER

CONFIDENTIALITY REVIEW

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Wayne, New Jersey
Monday, January 18, 2010

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Videotaped Deposition of PHYLLIS A. LAMBRIDIS, held at Ramada Inn, 334 US Rt. 46, on the above date, beginning at 9:06 a.m., before Kimberly A. Overwise, a Certified Realtime Reporter and Notary Public.

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I N D E X

E X H I B I T S

(Attached.)

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107	E-mail chain, Bates Nos. ACTAV000292438-439	56
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E X H I B I T S (Continued)

(Attached.)

E X H I B I T S (Continued)

(Attached.)

THE VIDEOGRAPHER: We are now on the record. My name is Catherine Smalfus. I am a videographer for Golkow technologies. Today's date is January 18th, 2010, and the time is 9:06 a.m. This deposition is being held in Wayne, New Jersey, In Re: Digitek Products Liability Litigation, for the United States District Court for the Southern District of West Virginia. The deponent is Phyllis A. Lambridis.

Will counsel please identify themselves.

MR. BLIZZARD: My name is Ed Blizzard. My law firm is called Blizzard, McCarthy & Nabers. It's located in Houston, Texas. And I'm here on behalf of Ms. Kelch and her family as well as other plaintiffs and as well as a member of the Plaintiffs' Steering Committee for the MDL.

MS. BRUERA: I'm Sofia Bruera. And I'm from Blizzard, McCarthy & Nabers, and I'm here on behalf of plaintiffs.

MR. PETTIT: Jim Pettit, Locks Law Firm, for various plaintiffs in New Jersey and as a member of the PSC.

MR. MILLER: Pete Miller from The Miller Firm here on behalf of plaintiffs.

MS. CARTER: Meghan Carter from Motley Rice on behalf of plaintiffs.

MR. MAZEY: Zack Mazey with Allen Guthrie & Thomas, Actavis liaison counsel in the MDL.

MS. AHERN: I'm Hunter Ahern from Shook Hardy & Bacon on behalf of Mylan defendants.

MR. ANDERTON: Michael Anderton with Tucker Ellis & West on behalf of the Actavis defendants.

MR. DEAN: And Richard Dean with Tucker Ellis & West in Cleveland on behalf of the Actavis defendants.

And let me just note briefly for the record that I certainly have no objection to Mr. Pettit or Mr. Miller asking questions in their role as members

of the plaintiffs' liaison committee in the Multidistrict Litigation. But the deposition was not cross-noticed at all in the New Jersey State cases, and Mr. Miller's notice in the Philadelphia cases is null and void on its face.

But, as I say, I have no objection to either of them asking questions in their role on the Plaintiffs' Steering Committee.

MR. MILLER: I'd like a little more clarification on how you feel the Philadelphia notice is null and void.

MR. DEAN: You can look at it and you can tell. So let's go ahead with the deposition.

THE VIDEOGRAPHER: The court reporter is Kim Overwise, and she will now swear in the witness.

- - -

...PHYLLIS A. LAMBRIDIS, after having been duly sworn, was examined and testified as follows:

BY MR. BLIZZARD:

Q Tell us your full name, please.

A Phyllis Ann Lambridis.

Q And where do you live, Ms. Lambridis?

A 19 Braemar Drive in Wayne, New Jersey.

Q Were you employed by Actavis at one point in time?

A Yes, I was.

Q During what period of time were you employed by Actavis?

A From September 2007 until December 1st, 2008.

Q Have you ever given a deposition before?

A Yes, I have.

Q On how many occasions?

A Twice.

Q What kind of cases?

A One was a divorce proceeding. And

one was with another job-related matter.

Q What job did you hold when you gave the deposition in connection with a job-related matter?

A Project manager.

Q For what company?

A Barr Laboratories.

Q And what year was that that you gave a deposition for Barr Laboratories?

A 1992.

Q So has it been a while since you've given sworn testimony in a deposition?

A Yes.

Q Have you had a chance to talk to the lawyers for Actavis, and have they reintroduced you to the concept of giving sworn testimony in a deposition?

A Yes.

Q So you understand that you're under oath here today?

A Yes.

Q You understand that you're required by the oath that you've taken to tell the truth?

A Yes.

Q You understand that I'm going to be asking you questions during the day; and if you don't understand one of my questions, you should tell me that you don't understand it and I'll try to repeat it or rephrase it so that at the end of the day we can be assured that we have accurate testimony from you in response to questions that you understood?

A Yes.

Q I'll try not to talk over your answers if you'll try to wait until I finish my questions. Although I grew up in Philadelphia, I've been in the south long enough that I talk kind of slow. And sometimes I don't quickly finish my question. So if you'll wait, be patient with me, I'll try to finish and then you can start your answer. Okay?

A Okay.

Q All right. You also have to give verbal responses to my questions. You can't just nod or shake your head because the court reporter will actually write down "nods head"

or "shakes head," but it's much better if you give a verbal response. Okay?

A Okay.

Q Are you represented by counsel here at the deposition today?

A No.

Q Have you had an opportunity to talk to Actavis counsel about what kinds of questions might be asked today?

A Yes.

Q On how many occasions did you meet with Actavis counsel in preparation for today's deposition?

A Three.

Q Could you tell me as best you can when those meetings were and how long they lasted?

A The first meeting was Monday of last week in the afternoon, half a day, so from about 1:30 to 5 o'clock; again on Thursday of last week. I'm sorry. I don't remember the dates. Same time frame, about 1:30 in the afternoon till 5:00.

Q Okay. Last Monday, I believe, was

January 11?

A 11th, yes.

Q And then you met again on Thursday of that same week?

A 14th.

Q And then how long did you meet on Thursday, the 14th?

A Again, the same time period, about 1:30 till 5:00.

Q And how about the third meeting?

A The third meeting was yesterday.

Q That would have been January 17?

A Correct.

Q And what time was that meeting?

A From about 7:00 till 8:00.

Q In the evening?

A In the evening.

Q Were you shown any documents during any of these meetings?

A One document, which was the redacted 483.

Q Okay. The 483 from --

A Issued --

Q From what period of time?

A May of 2008.

Q And that was the only document you were shown during the --

A Yes.

Q -- meetings that you had with counsel for Actavis?

A Yes.

Q What was discussed during the other eight to nine hours that you met?

A Procedural issues regarding the deposition; some of the things you mentioned to me just a few minutes ago about how to answer questions, to give full responses, to ask if I don't understand, ask them to repeat if I don't hear something; mostly procedural issues.

Some of the other items we talked about were my involvement with the Digitek recall and my interactions with FDA regarding that matter. That's about the majority of the discussion.

Q Okay. So the procedural issues about, you know, how to answer questions and make sure that you answer them fully -- I talk

slow but that couldn't have consumed that much time, could it?

A No. As I mentioned, we talked about the issues related to the Digitek recall --

Q Okay.

A -- and how much -- sequence of events and my interactions and how most of that unfolded.

Q Do you have a good memory of those things?

A Fairly good but I don't recall all of the detail.

Q Okay. What do you remember about the discussion with counsel about your involvement in the recall and your interactions with FDA?

A I'm sorry?

Q I'm sorry. What do you remember about your discussions with counsel for Actavis where you discussed your interaction with FDA and your involvement in the Digitek recall?

A Just the decision-making piece of that and who was contacted and involved in the

recall decision, what -- who spoke with FDA regarding the matter, some of the discussion that was part of the inspection that was ongoing with FDA and that interaction with FDA on-site. That was, you know, the details surrounding that.

Q Okay. Specifically what did you tell them about the details?

A Can you be -- can you ask me the question and I'll answer it? The question was, you know, who did you speak to? Who did you notify first? I talked to them about what was discussed with Erin, who was an investigator on-site, and then subsequent conversations with Actavis management and then with the FDA recall coordinator.

Q Erin is -- was one of the FDA investigators?

A Yes.

Q What was her last name?

A McCaffery.

Q And when did you first meet with her in conjunction with the inspection?

A The inspection began in March of

2008, middle of March. I think it was --

Q And --

A -- around St. Patrick's Day.

Q And is that when you first met with Erin McCaffery?

A Yes.

Q Were you the person who was in charge of interacting with FDA on behalf of Actavis concerning the inspection in March, April, and May of 2008, and the efforts that were made thereafter to correct the problems identified?

A Yes.

Q Is there anything that you've done to prepare for this deposition other than what we've discussed so far?

A No.

Q So the totality of your preparation has been meeting with counsel for Actavis on three occasions and also reviewing the FDA 483 that was issued in May of 2008 following an inspection of the Actavis facility at Little Falls?

A Yes, but I would like to note that

the 483 that was given to me, I only really read the first page. So I didn't review the whole document.

Q Now, before we talk about your time at Actavis, let me ask you about your educational background and your work history.

First of all, where did you go to school, undergrad? We can start there.

A My undergraduate was at Rutgers University.

Q And did you get a Bachelor's Degree from Rutgers?

A A Bachelor's Degree in microbiology.

Q What did you do after that?

A I was employed by Beecham, which is now part of Glaxo.

MR. DEAN: Excuse me, Ed. If it will speed things up, she does have a resume.

MR. BLIZZARD: Sure, that would be great.

MR. DEAN: However you want to go about it.

MR. BLIZZARD: Sure. That's

good.

(Plaintiff's Exhibit No. 105 was marked for identification.)

BY MR. BLIZZARD:

Q I've marked as Exhibit 107 a copy of your resume. Do you have another copy in front of you?

A No, I don't.

MR. BLIZZARD: I've already messed up on the exhibits. I'm going to re-mark this Exhibit 105 so we don't have any gaps. I'm going to put it up on this display device we call an Elmo so we all can read it.

BY MR. BLIZZARD:

Q I assume that your work history starts on Page 2 and then works its way up --

A Correct.

Q -- to the front.

Okay. So you were manager in the microbiology laboratory for Beecham?

A I started actually as a microbiologist at Beecham in the year I graduated, 1983. And then while I was

employed there, I began work for my Master's.

Q And then it looks like your next job was at Barr Laboratories; correct?

A Correct.

Q And Barr Laboratories, it says on this resume, is currently called Teva Pharmaceuticals; correct?

A Correct.

Q And it looks like you worked for them from 1987 until 1998; is that true?

A Yes.

Q And it shows, I think, on this resume that you started out as a manager in the microbiology laboratory and then moved up the ladder to ultimately a position as director of regulatory compliance; correct?

A Correct.

Q Now, did you get any additional education during this period of time?

A I started my Master's while I was employed at Beecham, and I completed it while I was working for Barr.

Q In what year?

A I believe it was 1990. If you go

down a little on the resume, you can -- oh, I didn't put the dates. I believe it was 1990.

Q So it was with Barr that you gave another deposition, you said, in about 1992; is that true?

A Correct.

Q And at that time it shows on your resume that you were a project manager?

A Correct.

Q Or associate director of quality assurance.

In what capacity were you working in when you gave your deposition?

A As the project manager.

Q In connection with what activity did you give your deposition?

A There was a court proceeding, US versus Barr Laboratories. And I participated in the preparation work for that activity, and I appeared at trial and then also gave a deposition.

Q When you say "appeared at trial," did you actually testify at trial?

A Yes, I did.

Q And this was a proceeding brought by the United States government against Barr Pharmaceuticals in the District Court in New Jersey?

A Yes.

Q And the government of the United States was trying to enjoin Barr Pharmaceuticals from making pharmaceuticals because they believed Barr was in violation of good manufacturing practices; is that correct?

A Yes, it is correct.

Q And you were involved in giving testimony defending Barr Pharmaceuticals?

A Yes.

Q And actually you have on your -- on other resumes that I've seen indicated your involvement in those proceedings; correct?

A Yes, that's correct.

Q In fact, you currently work for Halo Pharmaceuticals; is that right?

A Yes, that's correct.

Q And in the bio on the Halo web site, does it indicate that you actually were involved in the proceedings where the

government had tried to shut Barr down?

A Correct.

Q So you worked for Barr from -- ultimately you moved up to director of regulatory compliance; correct?

A Yes.

Q And then it looks like you worked for Schein Pharmaceuticals, which then became Watson Pharmaceuticals; is that true?

A Schein, yes.

Q And Schein, you worked as director of corporate quality standards, policies, and systems; is that right?

A Yes.

Q And for what period of time?

A From November of '98 until March of 2001.

Q And then going over to the first page of your resume -- well, let me ask you, first, why did you leave Barr Pharmaceuticals -- Barr Laboratories? I'm sorry.

A The opportunity presented itself with Schein. It was an opportunity and

actually quite a desirable offer. And so I had pretty much gone as far as I could in terms of career opportunities with Barr, and I decided to make a move over to Schein.

Q And then you stayed at Schein for, it looks like, about two and a half years?

A Yes.

Q Why did you leave Schein?

A Watson purchased Schein and roles and responsibilities were changing. And, again, another opportunity presented itself. I was -- when the company was put for sale, I started to look for other jobs and one came along. Even though I had been asked by Watson to stay, I decided to move on.

Q Did you not like the new management?

A Actually, that was one of the reasons.

Q The next time -- the next job you had looks like for Halsey Drug Company?

A Correct.

Q And that's currently named Acura Pharmaceutical; is that true?

A Yes.

Q And it looks like you worked for them from March of 2001 to April of 2003, according to your resume; is that true?

A Yes.

Q And your job there was, again, in compliance and quality?

A Correct.

Q And you were actually a vice president of the company and a corporate officer, weren't you?

A Correct.

Q What did -- why did you leave -- is it Halsey?

A Halsey.

Q Why did you leave there?

A Halsey was a very small company that was trying to do a number of different things, actually make a go of it, so to speak. And they were financially not very stable, and they were not doing very well at the time. And actually the site that I worked at was here in New York and subsequently was closing. So the only one that exists right now is the facility in Indiana.

Q In India?
A Indiana.
Q Indiana. Okay.
Then the next job you had was with Pliva, Inc.; is that right?
A Correct.
Q And what was your job there?
A Vice president of quality in New Jersey. That was the job I was hired for. And while I was employed -- Pliva was a Croatian company that had a site here in the US where I was employed. And then I was asked to go to Croatia where I spent approximately a year there working at that facility.
Q Did you again work in quality and compliance?
A Yes.
Q And you left them after two and a half years?
A Correct.
Q What was the reason you left them?
A Barr Laboratories bought Pliva.
Q So you're back to square one.
A I was back to square one.

Q Did you not like being at square one?

A I didn't mind necessarily except that Barr Laboratories wanted me to stay in Croatia.

Q That's a different kind of square, isn't it?

A It is.

Q So you left because you were essentially going to be required to stay in Croatia for Barr Laboratories?

A And my job here was now redundant, so...

Q Okay. So what was your next job?

A Actavis. Well, I'm a consultant. Back in 2003 when I left Halsey, I started a consulting firm. So I did do some consulting in the gap between leaving Halsey and being employed by Pliva. I still have that -- that company is still active.

And I may be skipping ahead here, but -- yeah, I'm skipping ahead. But I went from Pliva to Actavis. But I just wanted to note, because it just reminded me when I saw

that, that between Halsey and Pliva, there was a consulting opportunity.

Q Thank you for that. I noticed that you actually gave a presentation at a conference in 2004 in which you were noted to be employed by Framework?

A Okay.

Q And so you actually did work for this -- for your own consulting company --

A Correct.

Q -- in 2004 between your jobs for Halsey and Pliva?

A Correct.

Q And then after you left Actavis, you returned and did some additional consulting work again for your own company named Framework?

A Correct.

Q So you worked for Actavis, according to this, from September of 2007 to December of 2008; is that right?

A Correct.

Q And, again, for Actavis, you were in quality and compliance; is that true?

A Yes, it is.
Q And then for Framework, when you did consulting, you did consulting on quality system issues and compliance issues; correct?
A Correct.
Q And that's what you spoke about at the conference I noted.
A Yes.
Q And did you speak at other conferences?
A Yes.
Q How often did you speak on quality issues either during the time that you were employed by one of these pharmaceutical companies or as a consultant?
MR. DEAN: You want to clarify "speak"? At any conference or --
MR. BLIZZARD: Yes.
BY MR. BLIZZARD:
Q I don't mean speak as "I'm going to ask a question" kind of speak. I mean you actually were presenting to an audience at a conference.
A I would have to estimate about a

dozen times over the years.

Q Okay. When was the last time?

A June of last year.

Q 2009?

A 2009, yes.

Q And who sponsored that conference?

A New Jersey Pharmaceutical Quality Control Association.

Q What fancy place was it located at?

A Actually, it was at the Ramada Inn --

Q That's pretty fancy.

A The Ramada Inn, East Hanover, on the Turnpike, Route 10, I think it is.

Q And what was your presentation about?

A Oh, my goodness.

MR. DEAN: If you remember.

THE WITNESS: I'm trying to remember the title and I can't.

MR. DEAN: Could you give Mr. Blizzard the subject matter?

THE WITNESS: Yes, I can do that.

BY MR. BLIZZARD:

Q Sure.

A About FDA and some new guidelines and how to manage and use the information that you are obtaining in your facility to -- let me back up for a second.

There are new FDA guidelines that talk about how to -- what FDA's expectations are and how you can use the information within your own facility to enhance and improve and put continuous improvement in play based on information that you trend and gather as you do your job.

Q Okay. So it's about learning from your own experience, examining trends, and then making changes based upon those --

A Correct.

Q -- analyses?

A Uh-huh.

Q Is that true?

A True.

Q Okay. So your current job is what?

A My current job is with Halo Pharmaceutical as, again, vice president of

quality.

Q Now, I've noticed that since you moved out of working as a microbiologist, all of your work has been in quality assurance, quality control, compliance, and regulatory affairs; is that fair?

A Yes.

Q What do those terms mean in the pharmaceutical industry?

A I'm not sure I understand the question.

Q I really want the jury, who may not understand how pharmaceutical companies work, to have an understanding of the purpose of your job in quality assurance or quality control or compliance or regulatory affairs.

MR. DEAN: Could we take those one at a time since there are four of them there, Ed?

THE WITNESS: They are all different.

BY MR. BLIZZARD:

Q Let's take them one at a time. What is the purpose of quality assurance?

A Quality assurance is usually the group employed that does all the checks and balances throughout the operation, everything from sampling all the way through to the release of the product.

Q Okay.

A It also is the area that monitors the systems and gathers information for trending, et cetera.

Q Okay. So that's quality assurance. What is quality control?

A In most companies, quality control is defined as the laboratory operations that test the products, although in some companies, they use QA and QC interchangeably.

Q And so what is compliance?

A Compliance is a more broad term. And it really is defined differently from company to company. In most cases, my role was regulatory compliance, which was limited to FDA-related matters.

The broader term would be compliance with every agency. So it could be DEA. It could be OSHA, et cetera. But for my

purposes, the majority of my role has been with regulatory compliance and FDA-related matters.

Q And regulatory affairs, the purpose of the regulatory affairs department, as I understand it, is to interact with FDA about FDA regulations and compliance with those regulations?

A Regulatory affairs typically interacts with FDA mostly out of the Washington office and is part of the drug approval process. So that group is typically interacting with trying to get new drugs' applications approved and not necessarily in the day-to-day operation.

Q Okay. Have you worked in regulatory affairs?

A I've had regulatory affairs groups reporting in to me, yes.

Q Okay. So typically the regulatory affairs group is involved in submitting new drug applications or ANDAs; correct?

A Correct.

Q And also making sure they comply

with the regulations for keeping those applications current?

A Yes.

Q Which would include reporting of adverse drug experiences?

A Yes.

Q Now, with respect to quality control and quality assurance and compliance with FDA regulations and communicating with FDA about new drug applications and ANDAs, are all of those issues related to safety?

A It's one of the issues; but, yes, they all touch on safety.

Q And how do those functions of quality and compliance touch on safety?

A Well, I guess the best way that I could describe it is that when a new drug or a generic drug is approved, it's already gone through its review to determine that it's safe. And when you're working in the role as quality day to day, you're ensuring that the drug is manufactured in accordance with those formulas and procedures in that application. And you release the drug to market, provided

that it meets those specifications.

Q And so how do good manufacturing practices fit into that story?

MR. DEAN: Objection to form.

Go ahead.

Go ahead. You can answer.

THE WITNESS: Repeat that.

MR. BLIZZARD: Yeah. Let me change the question.

BY MR. BLIZZARD:

Q As I understand what you just said is that a new drug is approved or a generic drug is approved according to a particular formulation. And so quality is involved in making sure that the company actually makes the drug in accordance with the formulation that was approved as safe by the FDA; is that right?

A Yes.

Q Now, good manufacturing processes, are those things that have to be done to make sure that what is actually being manufactured is in accordance with what the FDA approved and is safe?

MR. DEAN: Same objection.
Go ahead. You can answer.
THE WITNESS: Okay. Not entirely.

BY MR. BLIZZARD:

Q Okay.

A Good manufacturing practices are the processes and procedures you put in place in your facility to ensure that the facility is run adequately.

Following the master formulas written is part of the -- is the compliance piece of that, but there are many other things that come into play when you're talking about the manufacturing practices. It has to do with everything from -- it's proceduralizing everything.

And there are laws written which are the GMPs; but they don't give you enough detail, and they don't tell you how to do it. So facilities have to interpret those laws and put procedures in place to comply with the drug regulations.

So there's the piece of it that has

to do with the manufacture of the drug, which is part of the drug application. And then the GMPs have to do with following the law.

Q Okay. These good manufacturing practices, are those standards set by the United States government for drug manufacturers to comply with?

A Yes.

Q And are those minimum standards?

A Yes.

Q And are the drug manufacturers expected to follow those by FDA?

A Yes.

Q Why do we have them?

A Food, Drug and Cosmetic Act, which to make sure that drugs that are released to the market are pure, safe, effective. I should know it by heart, but I don't know all the phraseology.

Q Okay. Let me see if this refreshes your memory. Do you recall that the GMPs are to ensure that the pills being made by the company, taken by Americans have the identity, strength, quality, and purity that they're

supposed to have?

A Yes.

Q Do the FDA regulations also require that the company have an effective quality control unit with appropriate responsibility and authority?

A Yes.

Q Now, you worked at Actavis, you said, in 2007 and 2008; correct?

A Yes.

Q According to FDA, during that period of time, was there a total failure of the quality system at Actavis?

A Can you repeat that?

Q Yes. During that period of time between 2007 and 2008, according to the FDA investigators, was there a total failure of the quality system?

A According to the investigator, yes.

Q I'm going to show you what I'm going to mark as 106 to your deposition.

Can we put up -- it's 543001.

(Plaintiff's Exhibit No. 106 was marked for identification.)

BY MR. BLIZZARD:

Q Do you have this document in front of you, Ms. Lambridis?

A Yes.

Q You can look at the document in front of you. We may be highlighting some of it on the screen. If you need to look at it there, you obviously can.

A I can't see it there.

Q But it might be easier for you to look at the document in front of you.

Does this appear from the title of the document to be an FDA Little Falls inspection closeout minutes?

A Yes.

Q And is the date of the minutes May 20th, 2008?

A Yes.

Q It shows who the FDA attendees were, and it shows Lisa Harlan and Erin McCaffery, who we mentioned earlier; correct?

A Correct.

Q And Erin McCaffery was, according to this document at least, the consumer safety

officer for FDA; is that true?

A Yes.

Q And the Actavis attendees included the executive chairman at the time, Robert Wessman, and yourself, who was vice president of US quality and compliance; correct?

A Correct.

Q And then also -- could you help me with the pronunciation? I think he's been referred to several times as Siggi.

A Siggi is correct. I believe it's Sigurdur.

Q Sigurdur, okay, Olafsson, who was CEO of Actavis, Inc.; correct?

A Correct.

Q And then it has Jeff Rope, vice president of operations, Actavis Totowa, and then Garret Wolan, who was the manager of compliance. Did he report to you?

A Indirectly. There was someone in between.

Q And there's a parentheses there that says "scribe."

Do you see that?

A Yes.
Q And does that indicate to you that he's the one who prepared these minutes?
A Yes.
Q If you look down to I guess it's the third paragraph, it says -- the paragraph that starts "Erin stated," do you see that?
A Yes.
Q Could you read that, those first two sentences for us?
A "Erin stated that one of the best outcomes of the Inspection was the input from the laboratory. Erin also said that from a Quality Systems standpoint, there was 'Total Failure.'"
Q And that's what you gave testimony to earlier; correct?
A Yes.
Q If you look over to Page 2, do you see the paragraph that starts "Robert Wessman" --
A Yes.
Q -- "stated that they stopped shipping product from Little Falls and hired

twelve consultants (PAREXEL) to review the products."

Do you see that?

A Yes.

Q So when was it that the company stopped shipping products from Little Falls and hired PAREXEL?

A End of April 2008.

Q So as of April of 2008, the company stopped completely shipping product from Little Falls and hired PAREXEL to review the products; correct?

A Yes.

Q And that would have included stopping selling Digitek; correct?

A Yes.

Q And also recalling Digitek about the same time; right?

A Yes.

Q And the investigators, it says, expressed additional concerns.

Do you see that?

A Yes.

Q It says -- first bullet says:

"Investigations on the 483 have still not been completed."

Do you see that?

A Yes.

Q Was there an explanation for that?

MR. DEAN: Excuse me.

Explanation given at the meeting, or does she have an explanation now?

BY MR. BLIZZARD:

Q Actually both. Was there an explanation given at the meeting for why the 483 investigations had not been completed as of the time of the closeout?

A I don't recall whether that was explained at that time.

Q Do you have an explanation for it, independent of what was discussed at the meeting?

A We were engaged in the inspection when some of these things had come to -- well, there were open investigations that were the subject of discussion during the inspection. And the people that would typically be involved with handling those investigations

were tied up with the inspection. So we didn't have them completed, but they were subsequently completed.

Q Okay. Do you know when they were completed?

A Various different times because we're talking about multiple investigations. But from what I can recall, there was a concerted effort at the close of the inspection to complete those investigations.

And we completed those and all of the others that were pending that summer, going into the fall. So I would say by the end of August, those were all completed.

Q Okay. The next bullet says: "FDA does not have final copies of recall letters."

Do you see that?

A Yes.

Q Was there a discussion of that at the meeting of why that had happened?

A Typically the minutes would reflect if there was discussion. So I don't know if it's in here at all, but I don't recall.

Q Okay. The next bullet says:

"Recalls have not been issued."

Do you know what that relates to?

A As I look at this, it looks like it's a recap of some of the concerns expressed over the course of the investigation. So it doesn't necessarily reflect the state of affairs at that point in time.

Q Okay. So the bullet point that says "Recalls have not been issued," are you saying that that doesn't really reflect the state of affairs as of May 20th?

A Correct.

Q Okay. The next bullet says: "Health hazards related to recalls are delinquent."

What does that mean?

A When you -- when there's a recall or you're considering a recall or you are -- you have a product that may be -- may potentially be a recall, the company typically would look for expert opinion, which they call a health hazard assessment, as to the nature of what the severity of the issue might be. And in some cases, the health hazard assessment

will -- might even tell you that there is no issue. And it helps you to justify to FDA why you may not do a recall.

In this particular case, we also -- companies would also do this because FDA is the final -- makes the final determination on the level of a recall, but a company would typically do their own health hazard assessment to try to work with FDA to minimize the impact of what level of -- you know, to determine what level, to talk with them and get their own personal assessment.

So in this particular case, we had done health hazard assessments on several of the products that were the subject of recalls that were in process; and they weren't satisfied with all of the content, or some of them were not timely.

Q Okay. So do you know whether one was done for Digitek?

A I honestly don't recall.

Q Do you know who did the health hazard analysis for Digitek if it was done?

A If it was done, it would have been

done by the same group that did the others, but I don't recall the name.

Q Was that PAREXEL?

A No.

Q Okay. Then who -- was it somebody within the Actavis corporate structure?

A No. It was an outside party. And it was someone more engaged in the medical field.

Q Okay. So some third party, if a health hazard analysis was done for Digitek, some third party outside the company would have done it?

A Yes. And that is typically done through -- it was requested through the pharmacovigilance group at Actavis. So an Actavis representative from that pharmacovigilance group, which was not part of my -- part of the regulatory group, worked with the consultant. So I don't know the consultant's name.

Q So you also don't know whether one was done at all or whether it was delinquent?

A For Digitek?

Q Yes.
A I don't recall.
Q Then the next bullet says: "That you put effective Quality Systems in place."
Do you see that?
A Yes.
Q And do you agree that as of May of 2008, there weren't effective quality systems in place for Actavis Totowa?
MR. DEAN: Object to the form.
Go ahead.
THE WITNESS: That was Erin's statement.
BY MR. BLIZZARD:
Q Okay. Did you agree with FDA on that issue?
A Not necessarily, no.
Q Did you agree with it at all?
A I agreed that that was her view and, based on what she had seen, that she had come to that conclusion.
Q And she was acting on behalf of FDA in coming to that conclusion; correct?
A Yes.

Q Do you see the next bullet says: "Get very nervous when you tell us that you are releasing product using the current Quality Systems (open issues remain)."

Do you see that?

A Yes.

Q Were you nervous -- well, let me stop you there.

Was there product still being released by the Little Falls plant at this period of time?

A As you pointed out earlier, the PAREXEL consultants were engaged the end of April. And at that point in time, we stopped shipping product, end of April. But after PAREXEL came in, they were reviewing product by product. And some additional products started to be released again based on the PAREXEL review.

Q And this -- sorry. Go ahead.

A I believe her statement here, she was referring to herself --

Q Right.

A -- that she gets nervous that we are

still releasing product.

Q And she's charged with making sure that US citizens receive safe drugs; correct?

MR. DEAN: Objection; calls for a legal conclusion.

Go ahead.

THE WITNESS: She's part of the organization that does that.

BY MR. BLIZZARD:

Q Right.

A As a consumer safety officer, yes, that's her job.

Q And then the next one, bullet point says: "Do not fix broken Systems - get new Systems. (I can't tell you what to do but start from scratch)."

Do you see that?

A Yes.

Q So you agreed with her that the system was broken and needed to be fixed?

A That's a very general statement. I think there were definitely systems that required some improvement. And there were still systems, I think, in place that were

working. So I would have to say I would agree perhaps on some of the issues and disagree on others. It would have to be more specific.

Q Which parts of the quality system, both quality assurance and quality control, did you think were broken and needed to be fixed?

A There were SOPs, I believe, that needed to be perhaps put into more detail regarding investigations and other things that she had noted that were obviously not the ones that weren't closed, et cetera, and some other areas.

I would have to go back and really look, but not -- when you referred to systems, FDA's view is there's six systems; and she's, I think, here not referring to the whole entire company. She's referring to the systems that she's looked at.

Q Right. And she's saying that they're broken and need to be fixed and you should start from scratch; right?

A That's her opinion, yes.

Q Right. And essentially did the

company do that?

A Eventually we did do that. We did assess everything, and we did improve or put new systems in place.

Q So you attempted to start from scratch, didn't you?

A In some cases. And in other cases, we borrowed procedures from other facilities, other Actavis facilities.

Q And you knew early on in the process of this inspection that FDA was not happy with Digitek and there were things that needed to be fixed; right?

A No, I wouldn't say that. The inspection started sometime in March. And I don't think the Digitek issue was discussed until sometime in April, so there was a month of inspection before Digitek was discussed.

Q Okay. Well --

A Approximately.

Q -- the inspection started about March 18th; correct?

A Right.

Q By April 9th, you knew they were

unhappy with Digitek, didn't you?

A I couldn't say. I don't...

(Plaintiff's Exhibit No. 107 was marked for identification.)

BY MR. BLIZZARD:

Q Let me show you what I'm going to hand you marked as Plaintiff's Exhibit 107, which is 292438. Do you see that this is an e-mail dated April 9, 2008, at the top?

A Yes.

Q And is it from you?

A Yes.

Q And its subject is "RE: Memo to FDA."

Is that true?

A Yes.

Q And if you look down, can you tell what the subject matter of this is from looking at this e-mail string?

A Yes.

Q What is the subject matter?

A It's a discussion between Chris Young and myself. Chris was the head of operations.

And the subject matter in the e-mail says "Memo to FDA." And the April 9th memo that I'm referring to was a document that we were preparing to give to FDA regarding actions we were going to take relative to what was happening with the inspection. It involved recall of other products, and it involved -- what he's referring to here about rationalization -- or actually what I'm asking him to do is we were having discussions with FDA about looking at our entire product line and then streamlining it.

So that's the subject of what started the e-mail chain, I guess. And then this note was my note again to Chris giving him feedback on what was discussed.

Q Okay. So it looks like the first e-mail is -- on the bottom of the page is from you to Chris Young, Subject: Memo to FDA, on 4/9/2008 at 11:21 a.m.; correct?

A Right.

Q And it asks him to write a piece to insert in the memo regarding the rationalization so that we can take care of it

at lunch today; correct?

A Correct.

Q And then about five minutes later, at 11:26 a.m., you write another e-mail; correct?

A Correct.

Q Again to Chris Young?

A It doesn't say.

Q Let's look at the top. So what's the body of the e-mail at the top say?

A That's from Chris back to me; and that's his answer, yes, from the previous, so if you go backwards.

Q So Chris responds back at 11:22, about a minute after you send him the e-mail, saying he'll prepare this paragraph containing the rationalization; correct?

A Correct.

Q And then if you look, if we go up top, you then send an e-mail back to somebody. It's not identified here. And it says: "She is not happy with the Digoxin. I think it's a recall on that batch. She is not happy with inspection and partial rejection/release as a

practice."

Is that what it says?

A Yes.

Q Do you know what that refers to?

A It refers to her review of digoxin. And the second sentence is referring to a batch that she reviewed that was the subject of the investigation. And my view from her comments was that she felt the batch needed to be recalled.

And then the last sentence is referring to the activities related to that inspection, which was an inspection and partial rejection/release of a product, so the fact that a batch would be inspected and then only part of the batch would be released and the other part would be rejected.

Q So when it says "She is not happy with the Digoxin," that's saying that the FDA investigator --

A It's referring to Erin.

Q Erin McCaffery; correct?

A Yes, yes.

Q So the FDA investigator was not

happy with digoxin; and you're saying, "I think it's a recall on that batch"; correct?

A Uh-huh.

Q And then you refer to the fact that she, again being the FDA investigator, Erin McCaffery, is not happy with inspection, partial rejection of a batch, and then release of the remaining batch, part of the batch; correct?

A Just in general.

Q Right.

A In general, she doesn't like that practice. It's not -- I mean...

Q In general, did you like that practice?

A It's an acceptable practice when it's on an exception basis. So FDA doesn't like to see that as a normal course of business, but there are occasions where it's very much warranted. It really depends on the situation.

Q Okay. Was it warranted on this occasion with respect to the Digitek investigation?

A The Digitek investigation, I wouldn't characterize that as a partial. When I think of a partial rejection -- well, I guess it depends on how you define "partial." But in my mind, "partial" means, you know, you make a huge batch and you are rejecting a substantial amount of that batch and then releasing the rest of it.

In this particular case, from what I recall with the digoxin, it was not a substantial part of the batch that had been rejected.

Q Okay. So with respect to the conduct of the company on the digoxin batch that is being -- was found to be partially released and partially rejected, are you comfortable signing off as a quality assurance professional and a compliance professional that that conduct was reasonable?

MR. DEAN: Objection; assumes facts not in evidence and misstates her prior testimony. I don't think she said that there was a partial rejection and release of any Digitek batch, as she

defined those terms. Now you're asking her to assume there was.

MR. BLIZZARD: Well, let me restate it, then.

BY MR. BLIZZARD:

Q As a quality assurance professional, are you standing by the conduct of Actavis in handling the Digitek batch at issue?

A I can't answer that question. For one thing, I didn't participate in the activities related to that, and I wasn't consulted on that matter. And I don't know the details of it, so I honestly can't answer that.

And you make a decision based on information that you have and the investigation that you do. And a lot of this is a judgment call. I can't make that determination now without looking at everything and determining the details of that.

Q So do you know who made the judgment call?

A I know who signed off on the

investigation.

Q Who signed off on the investigation and made the decision to partially release it?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: Dan Bitler, who was the QA director, I believe.

BY MR. BLIZZARD:

Q Okay. And so you can't say whether that was -- because you weren't involved and you don't know all the details, you can't say whether it was good judgment or bad judgment on Dan Bitler's behalf; correct?

A In hindsight, I may have one opinion. At the time, I would probably have another.

Q Okay. At the time, what was your opinion?

A No. What I'm saying is if I had been consulted on the matter --

Q Right.

A -- I would have more detail and I could make a better judgment call.

Q Okay. Do you have --

A But I don't have the detail. I only know what was presented in the investigation report that was written. And I don't recall most of that at this point in time.

Q So either at the time or in hindsight, can you say whether it was good or bad judgment on behalf of Dan Bitler?

A I really find that hard to answer. And I'm not trying to be difficult. We're sitting here -- I'm sitting here in a room full of lawyers, so I wish that Dan had not released that batch.

But as a professional and looking at a situation, there have been other cases where product has been released under the same circumstances and it's been fine and there have been no issues. And even if FDA may not have been pleased with the activity, there were -- it didn't result in what we're doing now.

Q Who did Dan Bitler report to?

A Dan Bitler reported to Scott Talbot.

Q And who did Scott Talbot report to?

A Scott Talbot reported to me.

Q And Dan Bitler's job was what?

A He was the director of QA for the Little Falls site. And the majority of his job -- well, his job was all of the in-process controls, all of the sampling, the group of -- the quality individuals that do the sampling, and all of the batch-related work up to and including the release of the product.

And Dan also handled investigations. He was part of the group of people that would write and approve investigations.

Q Was Dan fired after this inspection?

A Dan was let go. It was not characterized as fired.

Q What's the difference between "firing" and "letting go"?

A There were changes -- there was no cause. It was not for cause. It was a restructuring.

Q Okay. So who -- so there was no job left for him?

A There were -- the position was allocated to -- there were redundancies. So there was another QA director, and there were

also people at other Actavis facilities that filled the role.

Q When was Dan Bitler let go?

A I honestly don't recall.

Q Who was involved in letting him go?

A I believe I sat in on that discussion. It was with human resources and with legal, as with most.

Q And what do you recall about the discussion?

MR. DEAN: Let me just caution you if there was actual legal advice given, you shouldn't reveal that. But as far as personnel decisions, it's fine to answer Mr. Blizzard's question.

THE WITNESS: I can't even recall the detail. Basically, that we were making changes.

BY MR. BLIZZARD:

Q Had you known Dan Bitler before?

A I had -- I knew him in terms of my visits to the site, and I knew him as he assisted with getting information for the inspections. That was the most interaction.

Q What was he told about being let go?

A That we were making some changes and that we brought some folks from the Elizabeth facility in to help with lending us some of the procedures that they had in place and their experience in batch release, putting some new procedures in place there, and actually moved personnel from that facility over.

MR. DEAN: Excuse me. We've been going about an hour and ten minutes. If you want to go ahead for a few more minutes, that's fine; but when we reach a good breaking point --

MR. BLIZZARD: No. We can take a break.

THE VIDEOGRAPHER: We are now going off the record. This is the end of Videotape No. 1. The time is 10:17.

(Short recess.)

THE VIDEOGRAPHER: We are now back on the record. This is the beginning of Videotape No. 2. The time is 10:39.

BY MR. BLIZZARD:

Q Good morning, Ms. Lambridis. We're back on the record after taking a break. Are you ready to proceed?

A Yes.

MR. DEAN: Excuse me. Can we get the appearance here?

MR. TRAMMELL: Fletch Trammell for plaintiffs.

MR. DEAN: For which plaintiff, Fletch? Which litigation? The MDL?

MR. TRAMMELL: MDL.

MR. DEAN: Thank you.

(Plaintiff's Exhibit No. 108 was marked for identification.)

BY MR. BLIZZARD:

Q When we went off the record, we were talking about Dan Bitler being let go. I've now marked as Exhibit No. 108 to the deposition a copy of a document that starts or ends with Bates Nos. 918567. Do you see that that document on Page 1 is described as a Corrective Action Plan?

A Yes.

Q And is it dated August 28th, 2008?
A Yes.
Q And so would this have been after the FDA inspection was completed?
A Yes.
Q During this period of time, was the company still making changes designed to correct problems that were identified by FDA during the inspection?
A Yes.
Q And was this corrective action plan part of that process?
A Yes.
Q What is -- strike that.
MR. WEINKOWITZ: Hello?
MR. BLIZZARD: Hey, Mike. This is Ed Blizzard.
MR. WEINKOWITZ: Hey, Ed. How are you?
MR. BLIZZARD: Good. Do you want to make your appearance for the record?
MR. WEINKOWITZ: This is Mike Weinkowitz with Levin, Fishbein, Sedran &

Berman, Philadelphia, Pennsylvania.

Thank you.

MR. BLIZZARD: Would you mind putting your phone on mute?

MR. WEINKOWITZ: I'm going. I'm going on mute.

MR. BLIZZARD: Thank you.

BY MR. BLIZZARD:

Q Corrective action plans, does that have a certain meaning in the quality and compliance profession?

A Yes. This was a voluntary plan put together to address FDA's issues. So it was considered a corrective action plan because it specifically was designed to not only respond to the 483 but to take it beyond that so that upon reinspection the site would have a successful inspection.

Q So this was not only to address past issues, but to make sure you didn't flunk any inspections in the future?

A Right.

Q And the corrective action plan included issues relating to Digitek; correct?

A I would have to refresh my memory. Can I look through the document?

Q Well, I'm not specifically referring to this document right now.

A Oh, okay.

Q But, generally speaking, were some of the corrective actions that were taken in response to the FDA's inspection related to Digitek?

A Some of them, yes.

Q And if you look at Page 18571 where there's a heading called "Status of Organizational Changes," do you see that paragraph?

A Yes.

Q Do you see that you're mentioned in the first paragraph of the organizational changes?

A Yes.

Q It says specifically: "Phyllis Lambridis, Vice President of US Quality & Compliance, reports directly to Mr. Olafsson."

Is that true?

A Yes.

Q And Mr. Olafsson was the CEO of Actavis worldwide, wasn't he?

A No. I believe that might be his title now, but at the time Mr. Olafsson was the deputy CEO to Robert Wessman. Robert Wessman was the global CEO of Actavis, and Mr. Olafsson was his deputy CEO.

Q Okay.

A The change that they're referring to here is that they each took a more involved role in the US operations. So Siggi became the CEO of Actavis, Inc., in the US. And then because he became CEO of Actavis, Inc., I now reported directly to him.

Q So you reported directly to the CEO of Actavis here in the United States?

A Yes.

Q And that was part of the organizational change that was made in response to the FDA inspection?

A Yes.

Q Also described here on the next page at the top, does it talk about Dan Bitler there?

A Yes.
Q Do you see where it says: "Dan Bitler was dismissed"?
Do you see that?
A Uh-huh.
Q Is there a difference between being fired and dismissed?
A I think dismissed can be dismissed in many different ways.
Q He was dismissed and new quality oversight was put in place with Tony Delicato being appointed director of QA for New Jersey SOD -- what's SOD?
A Solid oral dose.
Q -- and has QA responsibility for both of Actavis' New Jersey sites.
Did I read that right?
A Correct.
Q So Tony Delicato took over Dan Bitler's job at the Little Falls plant and also had responsibility for the other plant as well; correct?
A He did -- Tony Delicato was the director of QA in the Elizabeth facility. And

this change actually elevated him to a level of having oversight at both facilities for all of QA. So he didn't go directly into Dan's seat, but he took over all of the QA activities at the site. So it was Dan's role and other QA activities.

Q Now, this corrective action plan that we're looking at was dated in August of 2008; correct?

A Correct.

Q And you were talking about the CEOs for the company at that period of time; correct?

A Right.

Q Talking about Siggi and also Robert Wessman being the worldwide CEO; correct?

A Right.

Q Now, there actually was a CEO in April of 2008 over the Actavis Totowa that was -- he resigned; correct?

A There was really no CEO, single CEO. The Actavis, Inc., organization had three gentlemen that ran the organization.

Q So this is in April of 2008 we're

talking about?

A When I joined up until April when this change -- well, May 1st, I think, was the official date that Siggi took over in the CEO role.

Q Okay. So from 2007 until May 1 of 2008, who were the three people in charge of running the operation?

A Divya Patel, Steinthor Palsson, and Doug Boothe.

Q Doug Boothe, did you say?

A Yes.

Q Okay. The second one I may need help from you to spell that.

A Steinthor, S-T-E-I-N-T-H-O-R.

Q Okay. And the last name is Palsson?

A Palsson.

Q Is that spelled like we would spell Palsson here in the United States or are there two Ss?

A I can't recall. I think there might be two Ss, but I don't -- I don't remember.

Q Now, as of May of 2008, were any of those people allowed to continue to run the

company?

MR. DEAN: Objection to the form.

Go ahead.

THE WITNESS: In May, Divya was given new responsibilities and was head of the R&D -- his new role was head of R&D, research and development.

BY MR. BLIZZARD:

Q How about Doug Boothe?

A Doug Boothe now reported to Siggi along with the rest of the management team.

Q Okay. So he stayed on with the company and reported to Siggi?

A Yes. We all now reported in to Siggi.

Q Okay. But Doug Boothe stayed with the organization?

A Yes.

Q Until when?

A I believe he's still there.

Q And Mr. Palsson, did he stay with the organization?

A He did stay with the organization.

He is still employed; but at some later date, he did return to Iceland in a new role.

Q And Divya Patel, did he stay with the organization?

A No. Divya was there until August.

Q Of 2008?

A I believe it was August 2008.

Q And then what happened then?

A Divya left the company, and Doug Boothe became the CEO of Actavis in the US.

Q Now, Divya Patel, do you know what his involvement in Actavis was -- strike that.

Do you know what Divya Patel's involvement was with the predecessor to Actavis and then continuing into Actavis?

A I'm not sure what you mean by "predecessor to Actavis."

Q Do you know that Actavis purchased Amide or Amide Pharmaceuticals?

A Yes.

Q And do you know what Divya's role at -- how do you pronounce that?

A Amide.

Q -- Amide Pharmaceuticals was?

A I don't know his title, but he was an owner of that pharmaceutical company.

Q And was that pharmaceutical company essentially a family-owned business?

A Yes.

Q And were there a number of Patel family members employed by the company?

A Yes.

Q And did a number of those family members stay on once Actavis bought out Amide Pharmaceuticals?

A Yes.

Q And which Patels are you familiar with that continued to stay on and work for Actavis after the acquisition of Amide Pharmaceuticals, which Patel family members?

A Divya, Apurva, A-P-U-R-V-A.

Q Okay. You've told us what Divya's position was. What was Apurva's position?

A Apurva, at the time that I was employed, Apurva was in manufacturing operation at the Little Falls facility, so he was -- I believe he was in charge of manufacturing operations.

Q And were there any other Patels that were involved -- any family members of the Patel family who stayed on after the acquisition of Amide Pharmaceuticals and worked for Actavis?

A I cannot recall her first name in both cases. There was a sister with a different last name -- she had a married name. I can't remember what it was -- employed in the legal department. And his mom, I think it was Nila Patel. I'm not sure. She was employed at the Little Falls facility in more of an office manager's role.

Q Now, following the FDA inspection and through the time that you worked at the company, did any of these, the Patel family members, stay on with the company?

A Up until I left, I believe the only person that was still employed was the sister.

Q That was in the legal department?

A Correct.

Q Okay. Now, back at the time that this inspection was going on in April of 2007, did you communicate with Divya Patel about

what products should be fixed in what order?

A We talked about what products needed to be addressed in terms of reintroduction because we were discontinuing product as a result of some of the activities.

We had some discussion about the recalled products and what needed to be done to enable us to market them. Again, that was the initial part of that discussion.

Q And was Digitek among the recalled products?

A Yes. Well, the first recall didn't involve -- the first group of products that were recalled, Digitek was not -- Digitek stood alone. It was handled in a different manner because we did not market that product. It was marketed by another company.

Q Okay. And that other company was Mylan?

A Correct.

Q So the recall that was done for Digitek was handled separately because of Mylan's involvement; correct?

A And because we had already committed

to a group of products that were going to be recalled, and that was already underway when the Digitek issue was raised.

Q And that recall for the other products that you mentioned was a Class 2 recall; correct?

A I believe so.

Q And then the Digitek recall was a Class I recall?

A Yes.

Q And a Class I recall reaches to the consumer level; is that right?

A Correct.

Q And the reason for that is potential health hazard for people who are continuing to take it; correct?

A Usually. It's the severity of the issue. There's criteria that needs to be met.

Q Right. But there was discussion at time, at some time, wasn't there, about whether or not to reintroduce Digitek?

A There was discussion with Mylan regarding wanting to reintroduce Digitek.

Q Okay. And when did that occur?

A I couldn't give you an exact time, but sometime after the recall.

Q Who was the discussion between?

A I didn't participate in those discussions.

Q Do you know who did on behalf of Actavis?

A No, I don't.

Q Do you know who did on behalf of Mylan?

A No.

Q Did you have any interaction with people at Mylan about Digitek?

A The interaction that I had with Mylan on Digitek was regarding the execution of the recall.

Q And who was it at Mylan that you interacted with about execution of the recall?

A Michael. I don't recall his last name. He was a quality -- in a similar role as I, in quality.

Q Could it have been Michael Adams?

A That sounds familiar.

Q About how many occasions did you

have interaction with Michael Adams about the recall?

A There were several back-and-forth phone calls mainly to work on the press release, different iterations, and the recall letter and whatever else, correspondence that was needed. It was several phone calls or actually just several days at one point in time.

Q And you don't know what time period this is likely these calls took place?

A End of April.

(Plaintiff's Exhibit No. 109 was marked for identification.)

BY MR. BLIZZARD:

Q Now, I want to show you what I've marked as Exhibit 109 to your deposition. And it's a document that has ending numbers 475895.

Do you see that this is an e-mail from you on April 10, 2008?

A Yes.

Q And it's to Chris Young, who was head of operations at the time?

A Yes.

Q And Doug Boothe, who was one of the people running the company?

A Yes.

Q And Divya Patel, who was another person running the company; correct?

A Correct.

Q And Apurva Patel, who was Divya's brother and who was head of manufacturing; right?

A Yes.

Q And what does the first -- what do the first two sentences say?

A "Attached are the color coded product lists provided to FDA. For the products that we want to stop and fix can you give me a first pass on the order of priority that you would like them assessed."

Q Okay. And is this where you actually took a look at the products or listed the products that were going to be recalled and asked the management of the company to give you some idea of whether they had a priority for how the products were reassessed?

A Can you say that again, just repeat it?

Q Let me ask a different question.

Do you see where it says "For the products that we want to stop and fix" -- do you see that?

A Yes.

Q -- "can you give me a first pass on the order of priority that you would like them assessed."

So were you asking these management people to give you some idea of the priority order for reassessing these products that you were going to stop and fix?

A Yes. I can explain if I can just put it into context.

Q Sure.

A At this point in time, there were, as I had mentioned before, a group of products that we were recalling. There were several things going on. If you refer back to this memo --

MR. DEAN: "This" being 107?

THE WITNESS: -- 107 exhibit,

we made some commitments to FDA to recall product. And that was outlined in a memo that was given to the Agency.

In addition to that, we agreed -- because those recalls were full recalls, so they involved taking all of the product for those products off of the market, they were affectionately known as the stop-and-fix products.

So the plan at the time was to -- at least we had stopped obviously manufacturing and shipping them. And the plan at the time was to evaluate them to determine whether they would be reintroduced and what would be needed before they could be reintroduced.

And the reason for that is because in some cases there were method-related issues or issues that could improve the product that may -- would require a lot of resources or FDA review that would be a lengthy review. So it was a business decision as to whether they were worth spending the time

as opposed to spending that time and resource elsewhere.

So that's the context of what's there. So one of the things that we presented to FDA, again back to the Exhibit 107, on April 9th, the memo that's referred to here, this FDA memo, we committed to recalls of those products; but we also were doing this rationalization.

So that list consisted of the products, these stop-and-fix products, and then other products that we were, for business reasons, most likely going to discontinue, and then the products that would remain.

BY MR. BLIZZARD:

Q Okay. I think I understand. So what you're saying is there were these products that the company was -- we're calling stop-and-fix products, and digoxin was not a stop-and-fix product?

A No.

Q But if you look at Exhibit -- if we

go back to Exhibit 107, I think, which is Page 292438, and at the top, that exhibit you're referring to, Exhibit 107, is dated April 9, 2008.

And actually, while it may not have been a stop-and-fix product, it was a we-ain't-so-happy-with-it product at that time, wasn't it?

A Correct.

Q And you knew FDA was not happy with it; right?

A Yes.

Q And did the company ever try to fix Digitek?

A No.

Q Do you know why the company never tried to fix it and put it back on the market?

A I -- digoxin was a high-volume product that took a lot of resource away from other things. And it was a product that they were manufacturing for someone else and not necessarily for themselves.

So I think there was partly a business issue and partly a resource issue.

Efforts to reintroduce a product were put into the products that were owned by Actavis.

Q Okay. So no attempt was ever made to see if the Digitek manufacturing issues or the Digitek quality issues could be fixed?

A Correct.

Q Do you know if PAREXEL ever did a risk assessment on Digitek?

A I don't think so. PAREXEL did not do a risk assessment on any of the products that were recalled if I remember correctly. The efforts were engaged mainly to look at the product that was still on the market.

Q Now, the inspection, this FDA inspection we've been talking about all morning, it started on March the 18th of 2008; correct?

A Correct.

Q Who was Anthony Castellazzo?

A He was a QA director that reported in to Scott Talbot at the -- he was actually located at the Riverview facility in the same Actavis Totowa site.

Q Okay. So he reported to Scott

Talbot at an Actavis Totowa site. He was in quality?

A Yes.

Q And what was his specific job in quality?

A As I said, he was hired as a QA director. His role was at the Totowa site, which is Riverview. This was the building that was -- there was an effort underway to move the operations from the Little Falls facility on Main Street to the new site at Riverview. So his role was mainly at that facility, and he was preparing that site for the subsequent transfer.

(Plaintiff's Exhibit No. 110 was marked for identification.)

BY MR. BLIZZARD:

Q I'm going to show you what I'm going to mark as Exhibit No. 110 to your deposition. And this is a document with Bates numbers ending 542861.

A Okay.

Q What is Exhibit 110?

A A series of organizational charts.

Q And if you look over on the third page that starts 542863, does it show you're the head of Actavis US quality and compliance?
A Yes.
Q And if you look at the following page, does it show Tony Castellazzo on it?
A Yes.
Q And does it show that his job, at least as of the time of this organizational chart, was qualification and remediation?
A Yes.
Q And what is qualification and remediation?
MR. DEAN: Excuse me. I think it says "remedication."
MR. BLIZZARD: I think it does, too, but I'm not sure that that's what it means.
MR. DEAN: I'm not sure that's right, but that's what it says.
BY MR. BLIZZARD:
Q Let me ask the expert. What's that supposed to say?
A It was meant to be "remediation."

Q So what was the job of qualification and remediation?

A These charts don't have a date, but they appear to reflect the organization after Doug Boothe was CEO. So this is later in 2008.

Q Right. This also was after Dan Bitler was let go or dismissed also, wasn't it?

A Yes. And so when you --

MR. DEAN: The question was: What is qualification and remediation?

THE WITNESS: Right. So -- oh, well, I'm getting there.

MR. DEAN: Okay.

THE WITNESS: By this point in time -- again, Tony Castellazzo was hired as a QA director for the Riverview site. The purpose of the inspection was to move everything into the Riverview site.

So part of his initial responsibility was the qualification of that site, which was ongoing. And what had occurred by this point in time is

because that we had stopped manufacturing and there was other work, he was given a role in what we called remediation, which was he was assisting now with all of the activities related to the Little Falls product line and all of the activities to get ready for reinspection.

BY MR. BLIZZARD:

Q Okay. Did he -- right before the FDA inspection, do you recall him writing an e-mail to you accusing you of being disengaged from your work?

A Yes.

(Plaintiff's Exhibit No. 111 was marked for identification.)

BY MR. BLIZZARD:

Q Let me show you what's marked as Exhibit No. 111. It's Document No. 609595. It actually starts with Page No. 94, but we'll start discussing it over on Page 95.

Do you see that there's an e-mail -- the first e-mail is dated March 16, 2008, at 5:40 p.m. from Anthony Castellazzo to you?

A Yes.

Q Do you have a specific memory of this e-mail?
A Yes.
Q Why?
A I was just surprised that, given his level, that he would write such an e-mail to me, the tone of it.
Q What do you mean by that?
A Just questioning the -- I just was offended by it actually.
Q He had not attended any school for diplomacy?
A Exactly. And he tended to be a little -- blowing things out of proportion.
Q So he says here: "For reasons which I can't confirm, you and I are not communicating and that's troubling. I was surprised that you weren't able to call into Friday's FDA readiness meeting given it's apparent urgency."
Now, was this meeting a meeting that was being conducted in preparation for the FDA inspection that we've been talking about?
A Yes.

Q He then says: "Perhaps the FDA is not coming on Monday, but next week" -- "but next week and thus the meeting lacked the sense of urgency for you. If that's the case, that's information the group should know. I found it rather curious that in your absence you would ask Dan Bitler rather than me to run the meeting. Not to mention that the director of technical services called the initial meeting."

Then in the next paragraph, does he say: "I may be reading too much into this, but your behavior of late strikes me as someone who has disengaged themselves from the process, and as a result given the impression that you may have alternative plans. I hope your not going to throw in the towel so soon."

Was there -- how long had there been meetings in preparation for this FDA inspection?

A There were several weeks of meetings, so this would not have been the first.

Q And was there discussion in some of

these meetings leading up to the FDA inspection that there were problems within the quality system?

A No. Tony was very frustrated in the fact that he was hired actually prior to when I started, so he was on board before September 2007 and had been waiting anxiously. So his references are mostly about getting the product moved over to the other facility and some of the issues related to delays in that occurring.

Q But when he says "throw in the towel," doesn't that suggest that there were problems such that people might want to give up?

MR. DEAN: Objection; calls for her to speculate as to what was in his mind.

BY MR. BLIZZARD:

Q Do you know what he was referring to when he said "throw in the towel"?

A It was mostly frustration from getting cooperation to get things up and ready. It was not necessarily referring to

systems and practices because his engagement in his role was not in the day-to-day activities going on at the Little Falls site.

Q And did you write a response to him?

A Yes.

Q And is that the e-mail that's on Page 1 of this document, which is dated Monday, March 17th, 2008?

A Yes.

Q And is this the actual day before the inspection started?

A Yes.

Q And if you look at the second paragraph -- actually, you start out this e-mail saying: "While the FDA inspection at Riverview is important it is only one of the many urgent issues I need to attend to."

A Yes.

Q What other urgent issues were you having to attend to at that time?

A I was head of all the US sites, so there were multiple sites within my purview of responsibility that were scattered along the East Coast.

And in addition to that, there were third-party manufacturers that we did business with that manufactured product for us. So I also had a group that had oversight of that. So there were things I was dealing with every day, not just that one site.

Q If you look at the beginning of the second paragraph, what does it say there?

A "My behavior of late," is that the paragraph?

Q Yes.

A "'My behavior of late' is a result of being exhausted, both physically and mentally. In case you are not aware we just had a major recall for one of our most important products. This was a huge distraction and took up a lot of my time. It unfortunately could not be avoided. I recognize that I have not had a lot of time to spend in Riverview. I am offended by your comment about being disengaged. I spent two weeks at Corium during their FDA inspection and countless hours both in the office and at home working on the recall, investigations,

and various other projects. Your perception is wrong."

Q Okay. So you were sort of setting him straight that you were working hard at the job responsibilities that you had at the time?

A Correct.

Q And they involved not just the Riverview facility but other facilities; correct?

A Correct.

Q They involved not just recalls at the Little Falls plant, but they involved other recalls; right?

A Well, at this particular time there were no other recalls.

Q And you indicated to him, kind of candidly, that you were -- that this work that you were engaged in at that time had caused you to be exhausted both physically and mentally?

A Yes.

Q Now, after the inspection which lasted, again, between March 18th and the closeout on May the 20th of 2008, was there a

list of responsibilities assigned to various members of the Actavis team?

A There were many lists.

Q I may just show you one of them, but let me just ask you before we get to the list, I want to talk about your responsibilities following the FDA inspection. Were you responsible for putting together the corrective action plan?

A Yes.

Q Were you responsible for designing the stability plan?

A That does not sound familiar.

Q Okay. Were you responsible for establishing a compendial review system?

MR. DEAN: Was that "compendial"?

MR. BLIZZARD: Yes.

MR. DEAN: Okay. Thank you.

THE WITNESS: There was discussion about that, but that was not within the context of the inspection.

BY MR. BLIZZARD:

Q Okay. Well, whether it was part of

the inspection or not, did you have that responsibility following the inspection?

A It would fall in my area.

Q Were you involved in developing a laboratory strategy?

A Yes.

Q Were you responsible for designing the format for weekly reports to FDA?

A Yes.

Q Were you responsible for preparing the response to the FDA 483?

A Yes.

Q Were you responsible for putting in place a universal recall process?

A The only thing I -- yes, but I want to just clarify that, not me personally, but it would fall in my area of responsibility. So it would be done by -- it would be delegated to the appropriate person in my group, in the quality group.

Q Were you responsible for preparing -- for putting in place -- for finalizing the quality organization for Totowa?

A Yes.

Q Were you responsible for refresher GMP training for employees who were involved in manufacturing or in the quality group?

A Yes.

Q Were you involved in or responsible for the risk review of products remaining on the market?

A Involved in I would say, yes.

Q Were you responsible for doing the protocol for the risk assessments that were going to be done for products remaining on the market?

A That was really -- that protocol was designed by the consultant team, PAREXEL. So my role would have been in approving that.

Q Were you also involved in establishing the analytical remediation group?

A Yes.

Q And were you responsible for establishing the strategy for evaluation of test methods?

A That would have been shared with the other function because I don't have that

expertise. We had called in help from the R&D group for that.

(Plaintiff's Exhibit No. 112 was marked for identification.)

BY MR. BLIZZARD:

Q I'm going to show you what I've marked as Exhibit No. 112 to your deposition, which is Document 1863647.

Could you tell me what this appears to be?

A I'm not familiar with this document.

Q Okay. Do you see where it's entitled, at least on the first page, "Totowa FDA Audit"?

A Yes.

Q And there's a list of people on the first page. And you're one of the people listed; correct?

A Yes.

Q It looks like a spreadsheet format, doesn't it?

A Excel spreadsheet, it looks like.

Q And it says "Who Attended Meeting," and then it has a list of dates for the

meetings and either a "yes" or a "no" next to each; correct?

A Correct.

Q And it looks like that you -- looking at the dates, were these meetings with FDA?

A The only one that I can see that was reflective of a meeting with FDA is the 20th, which was the day that they issued the 483.

Q Okay.

A I think it was intended to be reflective of internal meetings.

Q Okay. So it shows for the meetings on May 17th, May 18th, May 19th, May 20th, and another meeting on May 20th, it looks like you attended them all; correct?

A Correct.

Q And then if you look at the -- beginning on the fifth page of this document, which is Page 51, is there a list of what appears to be who's responsible for what, who will do what, the project area, and action list as part of this Excel spreadsheet?

A Yes.

Q Okay. And I'm not going to go through each of these, but does -- the first one on Line 10, it says: Project area, FDA communication; category, CAPA; Who is you; correct?

A Correct.

Q And then it says: "Put together an overall Corrective Action Plan that outlines our commitments, action items and the activities we will engage in to address FDA's concerns."

Do you see that?

A Correct.

Q And that was one of the responsibilities that you had; is that true?

A Yes.

Q And if you just kind of flip through the remainder of the document, does it appear that you were in this document, at least according to this document, assigned other responsibilities that we discussed here?

A Yes, I was assigned other responsibilities.

Was that your question?

Q Yes. And some of those we've discussed a minute ago, such as developing a laboratory strategy and other things?

A Yes.

Q Now, this document, although you're not familiar with it, it obviously was prepared after the FDA inspection; correct?

A No. Actually, it was before because the FDA inspection ended on May 20th.

Q So it was prepared sometime before the inspection ended?

A Yes.

Q Now, did you meet with FDA on a number of occasions in connection with their inspection at Actavis that we've been discussing today?

A I hosted the inspections if that's what you're referring to. I was present when FDA was on-site.

Q When you say "hosted the inspections," I'm thinking of coffee and tea.

A Yes, coffee and tea, I wish.

Q No cake?

A I was the point person for that

inspection.

Q And how many different meetings do you recall?

A She was on-site --

MR. DEAN: "She" being Erin?

THE WITNESS: -- Erin, from March 18th until May 20th, but not every day. So I don't know how many days of actual visits there were.

BY MR. BLIZZARD:

Q Have you ever heard of an EIR before?

A Yes.

Q What is an EIR?

A An EIR is an establishment inspection report. And it's the report written by the lead investigator for any FDA inspection. It's their internal report that they write to their management.

Q I'm going to hand you what I think has previously been marked as Plaintiff's Exhibit No. 91. And it doesn't actually have a Bates number on it because we obtained this through a request to the FDA under the Freedom

of Information Act. So I'm showing you what we received from FDA.

Have you ever seen the EIR for the inspection that was done by FDA of Actavis between March 18th, 2008, and May 20th, 2008?

A No.

Q If you look down at the summary on the bottom of the first page, do you see where it says in the middle of the first paragraph: "The inspection provided general GMP coverage"?

A Yes.

Q What does that mean?

A That was the type of category of the inspection.

Q So it says right after that: "Preapproval coverage was planned but not conducted."

What's the difference between preapproval coverage and GMP coverage?

A Preapproval is used in many different contexts. In this particular case, it was -- the inspection was held at the Riverview facility. And that, as I had

mentioned earlier, was a new building that we were planning to move into.

So the context of that inspection was to come in and give a preapproval of that facility so that we could move into it. So that's the preapproval part of it. And as part of any preapproval inspection, they also do a GMP inspection.

Q Okay. So what this was originally -- was this originally a preapproval inspection, but it turned into a GMP inspection?

A It was originally a preapproval inspection which would have included GMP, but we -- she started doing the GMP portion of it, and we never got to the preapproval portion of it.

Q If you look over on the next page, Page 2, you see where it says beginning on the -- I guess it's the first full sentence on that page, "The previous inspection"?

Do you see that sentence?

A Yes.

Q The previous inspection of the

Little Falls, New Jersey, facility provided coverage of the quality, production, laboratory control, materials and facilities and equipment systems. Deficiencies were documented in the areas of field alerts, the stability testing program, and investigations.

And then the last sentence says: Corrections were promised for all observations. The inspection was classified as -- is that a VAI?

A Yes.

Q What is VAI?

A Voluntary action indicated.

Q So that refers to a previous inspection of the same facility; is that true?

A Actually, it's an inspection of the Little Falls facility on Main Street, not the Riverview facility, but it's all Actavis Totowa.

Q Okay. So it was an inspection of the Little Falls plant?

A Yes.

Q Were you involved at all in that inspection?

A That inspection took place just prior to my arrival, so it was in process when I started with Actavis. And my only involvement was to attend again the closeout meeting that they held at the completion of that inspection.

Q Did you actually -- were you provided with any of the 483 materials so that you could be familiar with the issues at the plant going forward?

A Yes.

Q So you were familiar with what findings had been made in 2006 regarding the Little Falls facility in the 483 inspection?

A No. This was 2007. This inspection that I'm referring to was September of 2007.

Q Okay. So did you know about an inspection in 2006 of the Little Falls facility?

A Yes.

Q And when did you learn about that?

A Actually, I was aware of it prior to joining the company.

Q How so?

A Because they had been issued a warning letter, and just normal surveillance as part of my job. I know -- I keep up on what's going on with other companies, and it's in the news --

Q So was it --

A Trade press.

Q I'm sorry.

A Sorry. That's okay.

Q So that was part of your role as a consultant or while you were working for another company?

A No. It was just knowledge I had prior to joining.

Q Okay. So you saw the warning letter that was issued in 2006 to Actavis regarding the Little Falls facility?

A Yes.

Q And that was as an industry observer, I guess?

A Correct.

Q Did you do any further research on that subject when you arrived at the company?

A No.

Q Did you do any review of the 483 or any of the other documents that were generated following that inspection about the observations that had been made by FDA?

A In which inspection are you referring to?

Q The 2006 inspection.

A No.

Q So did you ever review the company's response to the warning letter?

A I may have at a later date. My joining in September of 2007 -- that was the follow-up inspection to that warning letter. So the context of what's written here, she -- what typically happens in any of these reports is they will refer back to the prior inspection. So what happened here was they had another reinspection as a result of that warning letter. And this is the point in time where they were classified as "voluntary action indicated," so the warning letter was lifted.

Q So essentially what happened was the inspection -- the warning letter was issued in

2006, and then there was a follow-up inspection in 2007 immediately before you started to work for the company?

A It started before I joined, yes.

Q So then if we go to the next paragraph, this paragraph is referring to the 2008 inspection; correct?

A I'm sorry. Which page?

Q Page 2. I'm sorry. Next paragraph.

A Yes.

Q Okay. So it says: This inspection was limited to coverage of the quality system due to significant CGMP deficiencies including but not limited to out-of-specification in-process, finished product, and stability results for more than -- and somebody's redacted the number -- prescription pharmaceutical products; release of digoxin tablets, .125 milligrams, Lot 70924A2, following visual inspection of the -- and then there's another word blacked out -- to remove double thick tablets; failure of the quality unit to reject products not meeting specifications, to complete quality assurance

investigations, to expand investigations to other lots and products, to file NDA field alerts within time frames, and to respond to out-of-specification products on the marketplace. Analytical methods requiring remediation remained in use and approximately -- the number is blacked out -- prescription drug products had no analytical evaluations of impurities on stability. Written procedures were not followed and changes with potential product quality impact were not all reviewed and approved by the quality unit. No market action was taken by the quality unit for any products on the market at the initiation of the inspection, despite the confirmed out-of-specification in-process, finished product, and stability results.

Now, was that what the general description of the inspection in March of 2008 was about?

A Description of the outcome of the inspection.

Q And it says -- in the sentence just

after what we just read, does it say: "No comprehensive risk assessment or quality evaluation for all products on the market was conducted by the firm's Quality Unit prior to completion of the inspection"?

Is that what it says?

A Yes.

Q And is that true?

A Yes.

Q Okay. If you go over to Page 3, do you see where there's a description beginning on the bottom of the page: "On 3/18/08, I, Investigator Erin McCaffery"?

Do you see that?

A Yes.

Q And do you see where it talks about she showed up on March 18 at the facility for the inspection? And then at the end of the paragraph, does it indicate that you joined the inspection later that morning?

A Yes.

Q And then does it show that you and Apurva Patel and Scott Talbot provided all requested information and documentation and

arranged for meetings with additional personnel?

A Yes.

Q On the following page, does it indicate at the top that on April 7th of '08 a meeting was held with Divya Patel, executive chairman; Christopher Young, director of solid oral dosage; and Apurva Patel, managing director; and Phyllis Lambridis, vice president, US quality and compliance, to discuss inspectional findings and the lack of response to out-of-specification products which remained on the market?

Do you see that?

A Yes.

Q And was Digitek one of the products that was remaining on the market on April 7th of 2008?

A Digitek was still on the market at that time.

Q Right. And it was just a couple days later that you wrote the e-mail about Erin McCaffery being so unhappy with digoxin; correct?

A Correct.

Q And then if you go down to the middle paragraph that starts on April 9th, do you see that?

A Yes.

Q On April 9th, a written commitment was provided by yourself, and it shows it's Exhibit 12. And it says in the middle of the paragraph: "The letter also included a plan to stop and remediate numerous products/processes due to the current cGMP findings."

Correct?

A Yes.

Q Is that the stop-and-fix list that you talked about earlier?

A Yes.

Q And then it says at the last sentence: The District was formally notified of a probable Class I recall of digoxin tablets, .125 milligrams, and then it gives the lot number; correct?

A Correct.

Q Okay. Now, if you go over to

Page 5, do you see at the bottom of Page 5 there's a paragraph that begins On April 14th of '08?

A May 14th?

Q I'm sorry. You're right. May 14th of '08.

Do you see that?

A Yes.

Q It says: On May 14th, '08, Investigator McCaffery met with Ms. Gudrun -- how you do you pronounce that?

A Gudrun Eyjolfsdottir.

Q -- executive vice president, quality and compliance, Actavis Group.

Was she your boss?

A I reported to her. She was the vice president of quality global. So I had a reporting line in to her.

Q Was she an officer of the company?

A That I don't know.

Q Were you an officer of the US-based company?

A No.

Q It says you were meeting with FDA to

discuss the upcoming exit meeting; correct?

A Correct.

Q And then if you look at the top of the next page, does it say there: "Both Ms. Eyjolfsdottir and Ms. Lambridis acknowledged the severity of the cGMP deficiencies and stated the need for corrective actions, restructuring of the Quality Unit, and hiring"?

Do you see that?

A Yes.

Q And do you recall making that admission?

A Yes.

Q And it was accurate and correct?

A Based on what was presented to us, yes.

Q Right. And part of this, these deficiencies involved the drug Digitek; correct?

A Yes.

Q Now, if you'll go over to Page -- I'm going to skip a few pages now -- Page 15, do you see there's a paragraph there that

starts: On April 23 of '08, following our discussions, we were contacted by Ms. Lambridis, who stated that they had decided to stop distribution of all products until further notice?

A Yes.

Q So that would include Digitek; correct?

A Yes.

Q So not only was there a recall of Digitek, but there was a decision made to stop distribution of all Digitek; correct?

A Yes.

Q And then it says: "At that time, the firm" -- this is the next paragraph. "At that time, the firm did not commit to stopping manufacturing despite the numerous product quality issues identified."

Is that referring to other drugs?

A Yes.

Q Okay. So there was a firm commitment that was followed to not manufacture any more Digitek; correct?

Let me rephrase it.

A Yeah, I'm...
Q Back in April of '08, did Actavis commit to not only recall Digitek but to not manufacture any further Digitek at that point in time?
A I'm just trying to get my sequence of events. Give me a minute.
Q Okay.
A Once you recall a product, you're not making it anymore. So the commitments here really are referring mainly to the other products.
Q So you recall Digitek; and as part of the recall, you decided you weren't going to distribute it any further and you weren't going to manufacture it in the future unless you did something else; right?
A Correct.
Q And the something else never happened; right?
A Correct.
Q For business reasons; correct?
A Correct.
Q And it says in the next paragraph:

Although the firm -- it's the middle of that next paragraph. Although the firm intended to restructure -- do you see that sentence there?

A Yes.

Q -- the quality organization and continue hiring, they had difficulty hiring as per Ms. Lambridis. We also discussed our significant concern with the release of digoxin tablets, .125 milligrams, Lot No. 70924A2, following the findings of double thick tablets. The investigation was inconclusive and did not extend to all other lots or strengths of digoxin tablets.

Do you see that?

A Yes.

Q I want to focus on the hiring issue. What problems were you having hiring people at that time?

A Just availability of people, attracting people to work for Actavis, which was relatively unknown in the US. We are in a very competitive environment in New Jersey with so many pharmaceutical companies. So it's very difficult to attract people, number

one, because you're a generic and not one of the brand-name companies but also with Actavis being relatively unknown.

Q So you had a difficulty identifying and hiring qualified candidates?

A It wasn't easy. There was not a large selection.

Q Do you know whether that had been a problem that had existed for a number of years or whether that was a new problem?

A I think it's always a problem, and it's actually been an issue in most of the companies that I've worked for. We tend to rely on a lot of networking. So a lot of times, as with Actavis, when I joined Actavis, I would reach out to other people. And I did hire people that I worked with before to come join me again.

Q Do you know what efforts were made by Mr. Patel to hire people back in 2006 about the time of the FDA investigation?

A I would have no knowledge of that.

Q Now, if you'll go over to Page 23, this is the last paragraph at the bottom. Is

this talking about the Digitek lot number that we mentioned earlier?

A It appears to be referring to it.

Q This is the lot that Dan Bitler made the decision to release part of; correct?

A Correct.

Q And it says here beginning in the middle of the paragraph: "No explanation was provided for the failure to chemically analyze the tablets or to evaluate the thickness or weight of all tablets to determine a root cause."

So, as I understand it -- you tell me if I'm wrong -- they found some tablets that looked like they were too thick, might be twice the size of what the tablet should be, and they didn't chemically analyze the tablets; is that right?

A They didn't chemically analyze them, but the description of the tablets was that they were double. I never saw the tablets. But the way that they were described to me was that they were double, like two tablets stuck together.

Q And did anybody take any measurements of the tablets?
A Not that I'm aware.
Q And you've already indicated nobody chemically analyzed?
A Not that I was aware of.
Q So nobody ever tried to determine what caused the appearance of these tablets?
A I would say that they didn't use those -- they didn't use those types of analyses to analyze the tablets, but there was an investigation. And there were several -- from what I recall, there were several items discussed that could have caused it, but they couldn't definitively pin it down to one particular issue.
Q Okay. What did they do -- if they didn't measure them and they didn't chemically analyze them, what did they do to the pills in the batch?
A They did an inspection, a visual inspection.
Q So they looked at them?
A Yes.

Q How many people looked at them?
A I don't know the exact number of people, but it would have been a group of people.
Q How many pills are in a batch?
A This is a very large batch size, and I believe the -- I don't recall the exact number, but it was several million.
Q How long does it take to visually inspect several million pills?
A I don't know how long that would take. I mean, it would vary on how many people and the method of inspection. So...
Q Do you know any of the details on it?
A No.
Q Would you agree that visually inspecting pills like that is a crude way of analyzing?
MR. DEAN: Objection.
Go ahead.
THE WITNESS: Again, the way it was described to me was like they were two pills stuck together. So while I

would agree that visual inspection for that large a number of tablets might be a tedious exercise for some kind of defect, this was described to me as very obvious defect.

BY MR. BLIZZARD:

Q Actually, I think I was asking you whether there are more scientifically precise ways of doing it than visual inspection.

A I don't know that I can answer that because you would have to measure every tablet, and I don't know if that's practical.

Q Okay. Well, was a sample, additional sample of the tablets taken and chemically analyzed?

A I don't follow the logic in the chemical analysis piece.

Q Okay. Was there any chemical analysis done of the double-thick pills, for example, to determine whether or not they contained too much active ingredient or too much inert ingredient?

A That was not done.

Q And would you agree with what FDA

says here, that no analysis was done that could identify the root cause of the problem?

A I would say no -- I would object to saying no analysis. She's saying -- she's pointing out the areas that were not considered, but there were several areas in the document that was written for the investigation where they did -- the areas that they did look at as a possible root cause. They didn't determine the definitive cause.

Q Okay. So she says there was no explanation provided for the failure to chemically analyze the tablets.

Do you see that?

A Yes.

Q Did you provide any explanation to her for that?

A No.

Q Okay. She says here that she asked you and Mr. Talbot how they could assure that other tablets within the batch were not out of specification and that you were unable to do that; is that accurate?

A Can I just read this for a second?

Q Sure.

A Okay. Now can you repeat the question?

Q Yes. My question was: This FDA document says that Ms. McCaffery asked you and Mr. Talbot how you could assure that other tablets within the batch were not out of spec and whether or not you provided any assurance to them, to FDA, that tablets within that -- other tablets within that batch were not out of spec.

A Actually what it says here is that we could not provide evidence to assure that additional out-of-spec tablets would not be identified if we inspected it by thickness, weight, or chemical.

Q Right. So you're saying that you could not assure that if we did additional testing, that we wouldn't identify other out-of-spec tablets?

A I guess basically, yeah.

MR. BLIZZARD: Okay. We've got two or three minutes left on the tape, our videographer tells me. So do we want

to break now for lunch? Do we want to start a new tape? Whatever y'all want to do.

THE VIDEOGRAPHER: You know what, let's go off the record.

We are now going off the record. This is the end of Videotape No. 2. The time is 11:58.

(Luncheon recess taken from 11:58 a.m. to 1:10 p.m.)

THE VIDEOGRAPHER: We are now back on the record. This is the beginning of Videotape No. 3. The time is 1:10.

BY MR. BLIZZARD:

Q Ms. Lambridis, we took a break for lunch and we're back. Are you ready to proceed?

A Yes.

Q We've been talking about a recall of Digitek this morning, among other things. And I believe what we discussed was that there was indication in early April or April 9th or thereabouts that the FDA was not happy with

digoxin and there would likely be a recall of a batch of Digitek; is that right?

A Correct.

Q Did at some point in time that recall expand -- or that discussion of a recall expand from the one batch to all Digitek?

A Not during the inspection, no.

Q When was it that the recall of Digitek was expanded to all Digitek?

A A commitment was made to recall the one batch. And we were in the process of doing the necessary paperwork to execute that recall. And we received a call from the Agency, the recall coordinator, and she had inquired about the status of the recall and asked to speak with our CEO in Iceland.

Q And who was the recall coordinator?

A The district office had another -- had a newly appointed or a recently appointed recall coordinator. I believe her first name was Margaret. I'm not sure.

But the person who called was Mimi Remache, who was in a higher level position

but had been the recall coordinator for a number of years.

Q So the person who called Actavis was this Mimi Remache; correct?

A Yes.

Q And how do you spell her last name?

A R-E-M-A-C-H-E.

Q And she said what when she called?

MR. DEAN: Objection; assumes facts not in evidence as to the question you directed to this witness.

BY MR. BLIZZARD:

Q Okay. Well, let me ask it this way: Did you talk with her?

A I spoke with her, yes.

Q What did she say to you?

A She asked me for the contact information for our CEO, and she said she wanted to speak to him with regard to the Digitek recall.

Q Do you have any estimate of what date this was?

A April 23rd or 24th.

Q So you were in the process of

preparing documents to execute the recall of a single batch; correct?

A Yes.

Q And you started that process when?

A I recall mid-April as being the time frame.

Q And then this call would have come on the 23rd or 24th from the former recall coordinator at FDA, who then held a higher level position, Mimi Remache, and she asked to speak to the CEO?

A Correct.

Q Did she tell you anything else?

A She expressed concern over the fact that the recall -- they wanted a press release and that that press release for the recall was taking an inordinate amount of time to get to them, because they need to approve it before it goes out.

Q So the press release was supposed to be prepared by Actavis?

A Well, that was part of the delay because the press release -- we had to coordinate with Mylan and decide who and how

the press release was going to go.

Q So you were in the process of talking back and forth with Mylan when the recall coordinator or former recall coordinator called you about getting the CEO's number?

A Correct.

Q And did she indicate to you on the phone that she was proposing that the recall be extended to all lots of Digitek?

A No, we did not have that conversation.

Q When was it that you next heard about the recall after you had this call with Mimi?

A I got permission to provide her the information for contacting our CEO, reason being the office in Iceland was closed, so she needed another way to reach him.

Q So she needed his home number in Iceland?

A Well, it was a cell number that was given.

Q Okay. And who did you get

permission from?

A Our senior management in the US. And they tried to contact the right people to get the information.

Q And who was the senior -- the person in senior management that you talked to?

A John LaRocca.

Q And what was his job?

A Legal counsel.

Q Was he chief legal counsel for the company?

A I believe so.

Q And after that did you -- what did you next hear back about the recall?

A I received a call back from Robert Wessman indicating that I should try to get them the press release within an hour, an hour's time.

Q Now, Robert Wessman is the CEO who was located in Iceland whose cell number you were giving out?

A Correct.

Q And what did he say about -- or what did you say about whether you could get the

press release out in an hour?

A That we would do our best to try to do that, accommodate that.

Q Did it happen?

A No.

Q Why not?

A Because in a subsequent conversation with Mimi, she indicated to me that the recall was for all lots and not just one lot. And that was the first that I had heard of that.

Q And so was this the decision that had been made by Robert Wessman after talking to Mimi or was this a decision that was made by FDA?

A I do not know.

Q So Mimi called you back -- strike that.

You said you had a conversation with Mimi, and then you heard back from Robert Wessman saying that you need to get a press release out in an hour if you could.

A Uh-huh.

Q And then after that, you next heard that the recall was going to be as to all

lots?

A Correct.

Q When was that that you next heard? Was it within the hour, or was it more than an hour later?

A It -- I don't know but in a relatively short period of time, the same day, the same day in subsequent conversation.

Q So was paperwork prepared to recall all lots of Digitek?

A Eventually, yes.

Q Was there any additional conversation between you and Robert Wessman or you and Mimi or you and any other senior manager of Actavis about the recall before this paperwork to recall all Digitek lots was prepared?

A I was working with my staff on numerous things, including this recall, so I was not the only person speaking with Mimi. So I believe it's the conversation about it being all lots occurred with one of my staff who informed me, and then I had the conversation with Mimi asking: "Why all

lots?"

And she indicated to me that that was what was agreed to in her conversation with Robert. And I subsequently again went through the channels to reach Robert again myself and asked him, confirmed with him if he had, in fact, agreed to that, and he did.

Q Did you ask why?

A No.

Q Do you know why?

A No.

Q Do you know of anybody in the company that knew why other than Robert Wessman?

A No.

Q Do you know anything about the conversation between Mimi and Robert Wessman other than what you've told me?

A No.

(Plaintiff's Exhibit No. 113 was marked for identification.)

BY MR. BLIZZARD:

Q Now, I'm going to show you what's marked as Exhibit 113 to your deposition.

A Do you need this back?

MR. DEAN: Put that one back together.

MR. BLIZZARD: For now, yes. I may come back to it.

BY MR. BLIZZARD:

Q This has a Bates number ending in 526961. Now, this is entitled "URGENT: DRUG RECALL."

Correct?

A Yes.

Q Was it urgent?

A All recall letters are urgent.

Q And was this one, like the other recall letters, urgent?

A Yes.

Q And did you prepare this letter?

A It's a combination of people that participated in the preparation of it. Some of it is standard format. Some of it is our wording. And some of it actually is FDA's wording.

Q So it was prepared for your signature; is that true?

A Yes.
Q And it is dated April 24th of 2008; is that correct?
A Yes.
Q And is that either the day of or the day after the conversations that we just discussed between you and Mimi and Robert Wessman?
A That was, yeah, the approximate date that I had given.
Q Okay. And if you look over at Pages -- I guess it begins on Page 4 of 9, do you see that there are lists of lots to which this applies, this recall?
A Yes.
Q So does it appear from this document that you have in front of you that this recall notice was intended to be sent out as a recall of all lots of Digitek?
A Yes.
Q Okay. It says "Dear Valued Customer" on Page 1.
A Uh-huh.
Q Who was that addressed to?

A This is intended to be the letter that goes to whoever received the product so that they would have the information on the recall and know where to return the product.

Q Okay. So this is intended primarily for pharmacies?

A Whoever the customer is. So there has to be a chain of events that occurs. So in some cases, depending on who you sell to, if I send it to someone who's then distributed it further, then they would either use my recall letter to take it further or they would create their own recall letter for their own customers to return product back.

Q So you send it only to the people you sold to?

A Typically.

Q And so you would have sent this letter that has a date of April 24, 2008, to the people that you sold Digitek to?

A In the particular case of Digitek, it was sold to Mylan, who then sold it to others. So I don't know if this letter was sent to their customers or if they used their

own letter.

Q So is it your recollection -- well, let me back up.

Did Actavis sell to anybody besides Mylan?

A For digoxin, no.

Q Yes. Okay. So make sure we have a clear record, was there any other customer of Actavis for digoxin other than Mylan?

A No.

Q So when you say "Dear Valued Customer" here in this letter, you could have just as easily said "Dear Mylan"?

A Correct.

Q Then it says: "This is to inform you of a product recall involving "-- and then it lists Digitek .125 milligrams; correct? And then it says: "See Attached List for Lot Numbers/Expiration Dates."

Do you see that?

A Uh-huh.

Q Is that a yes?

A Oh, I'm sorry. Yes.

Q Okay. Then the paragraph that

starts, "This recall has been initiated due to overweight tablets," do you see that?

A Yes.

Q It says: "Potential risks to the patient depend upon the constituency of the tablets. Depending on the constituency of the tablets, double the dose is taken, it can be expected that digitalis toxicity can occur in individuals taking daily doses or in patients with renal insufficiency. Toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can result from excessive digitalis intake."

Is that what the letter says?

A Yes.

Q Based upon your knowledge of Digitek, is that accurate?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: I don't have the expertise.

BY MR. BLIZZARD:

Q Okay. Well, when you agreed to have

your name associated with this letter, did you consult with people who did have expertise?

A Yes.

Q And so far as you know, is this information accurate?

A Yes.

Q Okay. Then it says: "If the increased thickness is due to clinically inert substances, then a decreased amount of digitalis may be absorbed, leading to exacerbation of the underlying cardiac disease (congestive heart failure)and arrhythmia) due to lack of therapeutic efficacy."

Is that what part of this letter says?

A Yes.

Q Again, I understand you're not a doctor. But based upon the other consultants that were utilized in the preparation of this letter, is that accurate?

A Yes.

Q And then it says: "Actavis has distributed the subject lots from" -- and then there's some dates that haven't been filled in

yet.

And it says: "This recall should be carried out to the consumer level."

Is that correct?

A Yes.

Q Why was it to be carried out to the consumer level?

A Because FDA had indicated that it would be a Class I recall. And a Class I recall goes to the consumer level.

Q What is it that differentiates Class I recalls from Class 2 recalls?

A The severity of the issue.

Q Okay. So the potential health hazard involved is part of the decision making?

A Yes.

Q And was that true with respect to this recall of Digitek?

A Based on what was characterized here as the health hazard, yes.

Q Right. Okay. Then it says here: "Upon receipt of this letter, please take the following action." It says: "Immediately

examine your inventory and quarantine and discontinue distribution of the affected lots."

Again, that's being -- you're telling Mylan that in this letter; correct?

A Yes.

Q And then it says: In addition, if you may have further distributed the recalled product, please identify your retail-level consumers and notify them at once of this product recall.

Do you see that?

A Yes.

Q And then it says: "Additionally, if the retail-level customers have further distributed the recalled product, please identify the consumer and notify them immediately of this product recall."

Is that what that says?

A Yes.

Q Okay. So basically this letter is telling your valued customer to quarantine what's left, and anything you distributed to somebody else, try to get it back, and notify

them of the recall; and if it's been distributed further than that, then you should let those people you distributed it to know that they should try to get it back and inform people of the recall?

A Correct.

Q Now, did this letter go out on April 24th of 2008?

A I don't think so.

Q Do you know when it went out?

A Within the next few days.

Q Did you provide FDA with a copy?

A They always see the draft, which I believe this is the draft, because all the information is not in here. But they usually see a draft before it goes out.

Q Did you provide the entire recall package to FDA?

A There's different terminology when you talk about a recall package. So are we talking about the letter and what goes in that mailing, or are we talking about the documents that FDA requires for the recall? Those are two different.

Q Okay. Let me direct you to something that may help clarify for me my question and then maybe your answer. If you'll look at Page 19 of Exhibit 112, the EIR -- oh, actually, it's not 112.

MR. DEAN: 91.

BY MR. BLIZZARD:

Q It's 91.

A 91. Page 19?

Q Page 19, yes. Do you see at the top of Page 19, the paragraph that begins "Additionally"?

A Uh-huh.

Q It says: Additionally, despite the ten-day time frame to provide recall information to the FDA following notification of a voluntary recall, no completed recall packages for any of the recalls had been provided at the time of the exit meeting on May 20th, '08. Phyllis Lambridis, vice president, quality and compliance, acknowledged the delay.

Do you see that?

A Yes.

Q Could you explain to me what that's referring to?

A That's why I asked the question, because there's a terminology used when you conduct a recall that's called a recall package. And in the context of what they're talking about here, that recall package is documentation that FDA requires whenever a recall is done.

So that recall package, if it's one batch, it's typically that entire batch record, all the distribution for that product, the active ingredient, where the active ingredient came from, a whole series of documents that makes up everything from beginning to end on -- from when you first received the raw material through the actual distribution into the market.

So those packages had to be made for any recall that we did. And, as you know, we did a substantial amount in addition to the --

Q Digitek?

A -- Digitek. So all those packages had to be assembled and sent to the Agency,

and that's what they're referring to here.

Q So you acknowledge in your meeting with FDA that you were late with the recall packages?

A Yes.

Q Do you know when this letter that was prepared for your signature actually went out?

A I don't know the exact date.

Q Did it go out under your signature?

A Yes.

Q Did it go out only to Mylan?

A I believe so.

Q And do you know what Mylan did with it after that?

A No.

Q Now, do you know what a tableting equipment with weight controls are or is?

A Yes.

Q Tell me what tableting equipment with weight controls is.

A It's a tablet press that has a computerized mechanism in it to weigh tablets and adjust weights, so it's automated.

Q So if you put the appropriate settings in and the tablet somehow comes out over- or underweight, the press automatically adjusts for that so that you're getting uniformly weighted tablets?

A That's my understanding.

(Phone interruption.)

MR. BLIZZARD: That doesn't mean the deposition's over.

MR. ANDERTON: That's what she said.

BY MR. BLIZZARD:

Q So I'm going to show you a document that's marked as -- or I'm going to mark as Exhibit 114 to your deposition.

So this e-mail has actually number on it, 140102.

MR. DEAN: No, that's not the number mine has, is it?

THE WITNESS: Is that the correct one?

MR. BLIZZARD: No. It is the correct one, but I picked up another one.

MR. DEAN: Do you need this

back?

MR. BLIZZARD: Well, I guess I have a duplicate. What number do you have?

THE WITNESS: The page number?

MR. BLIZZARD: Yes.

MR. DEAN: The Bates number.

THE WITNESS: 142150.

(Plaintiff's Exhibit No. 114 was marked for identification.)

BY MR. BLIZZARD:

Q All right. We have it up on the screen here. But is this an e-mail that's dated April -- actually, there's a couple of e-mails on this document; correct?

A Yes.

Q The one at the bottom is the first one in time, is it not?

A Yes.

Q It's from a Kevin Anderson to you dated April 30th of 2008 at 9:16 a.m.; is that right?

A Yes.

Q And this is shortly after the recall

of all Digitek lots had been announced; is that true?

A Yes.

Q And it's regarding a conversation with a Mike Adams from Mylan; is that true?

A Yes.

Q It says: "I know you are trying to vaca this week."

Is that the verb for vacation?

A I think so.

Q So you were trying to vacay the week of April 30th. And then Mr. Anderson was talking to you about this conversation with Mike Adams wanting an update on Digitek; correct?

A Yes.

Q And then there's another e-mail on April the 30th at 10:42 from a Dan Bitler to you and Kevin Anderson; is that true?

MR. DEAN: No. It's from -- I think you misread that.

THE WITNESS: This one here in the middle?

BY MR. BLIZZARD:

Q Yeah. There's an e-mail from Dan Bitler in the middle, isn't there?

A Yes.

MR. DEAN: Okay.

BY MR. BLIZZARD:

Q Okay? From Dan Bitler to you and Kevin Anderson; correct?

A Yes.

Q It says: "I talked with Mike Adams this morning and gave him an overview of where we are with the inspection. I indicated that we expected the FDA back next week to issue the 483 and he indicated that he would like to talk with Phyllis briefly next week to discuss the timeline moving forward for Digoxin. He was satisfied with the information I provided and I indicated that we would contact him next week."

Is that what it says?

A Yes.

Q And then you write an e-mail at the top, is that right, top of this page?

A Yes.

Q And it's April 30th at 11:21 a.m.; is that right?
A Correct.
Q And then it says: "It is my understanding that Robert and Siggi" -- that's Robert Wessman and Siggi Olafsson?
A Correct.
Q -- "have committed to stop producing Digoxin until we have tableting equipment with weight controls."
Did I read that correctly?
A Yes.
Q Then it says: "Please do not have any conversations with customers unless you have the full story."
Is that what it says?
A Yes.
Q Okay. The customers would be Mylan; right?
A Yes.
Q And what was the full story?
A I didn't know what the full story was, so I was cautioning him on making any commitments or having conversations without

all the information.

Q Okay. Did you subsequently have any conversations with Mr. Wessman or Mr. Olafsson about the commitment to not produce any more digoxin until there was tableting equipment with weight controls?

A I was present during some of the discussions with senior management regarding Digitek. And the context of this was that they would not produce -- if they were going to move forward with digoxin, that they would want to purchase equipment with weight controls.

Q Okay. And I take it that there wasn't any existing equipment at the Little Falls or Riverview plant that was a press with weight controls; is that true?

A I'm not sure if there were none, but the presses -- majority of the presses there were not automated. So there might have been one. I'm not sure.

Q But there wasn't enough presses that were automated to produce digoxin with presses that were all weight controlled; is that true?

A Yes. But you have to keep in mind that the presses with weight control are automated presses that companies may or may not have, and that in the absence of the automated weight controls, it's done manually.

Q Was it important that digoxin, in particular, have properly weighted pills?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: It's important for any product produced to have...

BY MR. BLIZZARD:

Q Do you know whether digoxin has a narrow therapeutic window?

A I couldn't answer that. I don't...

Q Or a narrow toxicity window?

A I believe it's a toxic -- yes, it's a relatively potent compound.

Q So if the pills are not properly weighted, it could have a health impact on a patient; right?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: Yes.

MR. BLIZZARD: I'm going to show you the next document, which I'm going to mark as 115.

(Plaintiff's Exhibit No. 115 was marked for identification.)

MR. DEAN: Excuse me. Can we take just a two-minute break to see if there's a heat control?

MR. MILLER: I just asked Meghan to go check.

MR. BLIZZARD: Yes. I'm agreeing with you, but I don't want to get into a tug of war over the thermostat. I've had that before.

MR. ANDERTON: Ever win one?

MR. BLIZZARD: No.

MR. DEAN: We're going to lose some of us pretty quickly if we don't get an adjustment here.

MR. BLIZZARD: Let's take a quick break and see if we can fix it if that's okay with you.

THE VIDEOGRAPHER: Off the record, 1:44.

(Discussion off the record.)
THE VIDEOGRAPHER: Back on the record, 1:46.
BY MR. BLIZZARD:
Q Ms. Lambridis, we went off the record so we could talk about the temperature controls and we're back.
Are you ready to proceed?
A Yes.
Q Now, have you looked at this document that's dated April 28th, 2008?
A Yes.
Q Okay. I'm sorry. I didn't hear you.
Do you see it's from Mike Adams?
A Yes.
Q And he was the -- as I recall, we've identified him as a Mylan employee?
A Correct.
Q And he's writing to Vincent Mancinelli regarding a discussion with Actavis quality; is that right?
A Yes.
Q Now, do you know Mr. Mancinelli?

A No.

Q It says here that Chuck Koon and Becky Pinnell had an informal conversation with Dan Bitler, Actavis quality, regarding the ongoing FDA inspection of the Little Falls facility. And he's providing a brief summary below; correct?

A Yes.

Q Do you know Chuck Koon or Becky Pinnell?

A No.

Q It says: The company has halted production of all products at the Totowa Little Falls, New Jersey, site.

Is that accurate?

A Yes.

Q It says: "At this time they are not sure when they will resume manufacture of Digitek."

Is that correct?

Was that correct as of April 28th?

A Well, it's correct in that's what's stated here. Yeah, I guess that would be correct.

Q Okay. So to make it clear, it was correct that as of April 28th, the company was not sure when they would resume manufacture of Digitek; is that right?

A We were in the process of recalling product, so I doubt very much we were talking about resuming.

Q Then it says: "There is a rumor coming out of Actavis quality that the company has committed to purchase a new tablet press with appropriate weight control."

Do you see that?

A Yes.

Q Okay. And, again, that reflects what was being reported in the Actavis e-mails --

MR. DEAN: Objection.

BY MR. BLIZZARD:

Q -- true?

MR. DEAN: Calls for hearsay.

Go ahead.

THE WITNESS: Oh, referring back to my e-mail?

BY MR. BLIZZARD:

Q Yes. Your e-mail of April 30th indicated that the company would not resume manufacture without automated tableting equipment with weight control; correct?

A Yes.

Q Now, this one actually suggested Actavis is saying -- there's a rumor that Actavis has committed to purchase a new tablet press with appropriate weight control; correct?

A That's what it says.

MR. DEAN: Objection. Actavis doesn't say anything. Mylan is saying something.

BY MR. BLIZZARD:

Q I said in this Mylan document -- let me make it clear.

This Mylan document says that there's a rumor coming out of Actavis that the company has committed to purchase a new tablet press with appropriate weight control.

Is that what it says?

A Yes.

Q Did any -- was there any attempt that you're aware of to buy a new press with appropriate weight control during the time that you remained employed by Actavis?

A Not for Digitek.

Q Okay. Were there other automated presses bought with weight controls that were used to manufacture drugs other than Digitek after the FDA inspection?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: I can answer?

MR. DEAN: You can answer, sure.

THE WITNESS: We did evaluate that. I don't recall what was purchased or if anything was purchased.

BY MR. BLIZZARD:

Q Okay. So you don't know one way or the other?

A No.

Q In August of 2008, you were still employed with the company?

A In August, yes.

Q And there were -- the remediation effort or the effort on the corrective action plan, was it still underway at that time?

A Yes.

Q And had some of the items on the corrective action plan actually been completed?

A Yes.

Q Were there others that were incomplete in August of 2008?

A Yes.

Q Were there still significant weaknesses within the quality department and the quality system as of August of 2008?

A We were still in the process of putting together a robust quality system to inspect -- that would hold up to inspection. So I think that there was still a lot of work that needed to be done along those lines. I don't know that I can say there were weaknesses.

(Plaintiff's Exhibit No. 116 was marked for identification.)

BY MR. BLIZZARD:

Q Let me show you what I'm going to mark as Exhibit No. 116 to your deposition. And this ends in Bates numbers that are too small for me to read, 302466, I believe.

A 69.

Q 69. It's an e-mail dated August 14, 2008.

Is this an e-mail dated August 14, 2008, from Anthony Castellanno? Castellazzo. I'm sorry.

A Yes, correct.

Q And he sent it to a number of people and cc'd you?

A Yes.

Q And the subject of this e-mail is Assessment Meetings; is that correct?

A Yes.

Q It says here: "To All." And does it say: "It would be an understatement to say that I'm disappointed and perplexed over the low turn out for these assessment follow-up meetings"?

What was an assessment follow-up

meeting?

A One of the activities that we undertook in the corrective action plan was to have PAREXEL do an assessment of the existing quality systems and help us to identify areas that would require, you know, additional work or improvement to strengthen them up to be able to pass muster at the next inspection.

So it's sort of an internal audit of sorts whereby they provided assessments. And then the activity that's being referred to here is that people were assigned tasks to address the issues, whether it be writing an SOP or revising an SOP or doing some work to put some information together.

And Tony Castellazzo, as we mentioned earlier, part of his role now with all of the activities was to track, track the progress. So he would hold weekly meetings with the people that were assigned these tasks to get status reports.

Q Okay. And he was saying that people weren't showing up; right?

A Correct.

Q He says: "Initially, attendance was good. Then people were asked to commit to actions and report their status. Perhaps I haven't stressed the importance of addressing these observations many of which speak to significant weakness in our Quality System."

Is that what he wrote?

A That was what he wrote, yes.

Q Okay. And it says: "Several of these same weaknesses have also been noted in the recent 483."

And that's the 483 issued by FDA; is that right?

A Yes.

Q It says in the next paragraph: "In order to resolve the observations and strengthen our systems I need everyone's cooperation not just a select few."

Is that what he says?

A That's what's written, yes.

Q Did you support him on that?

A Support -- you have to be more specific. Did I support him in his opinion, or did I support him in the fact that everyone

needed to participate to work through the tasks?

Q That people needed to show up and it wasn't just a select few, but everyone who was assigned tasks needed to show up and take the actions they were committed to.

A I believe, yes, everyone needed to participate and do the work that was assigned.

But I want to just qualify that Tony Castellazzo tended to blow things out of proportion. And some of the reasons behind the meetings were that the meetings were not that productive in -- some of it was related to how he was conducting the meetings. So people were frustrated. Because I also had feedback from other areas telling me that the meetings weren't productive.

So you have to take this in the context of his frustration as opposed to people not taking active involvement in the activities.

Q Okay. Well, he was expressing to at least the group internally that, in his opinion, there were weaknesses in the quality

system still in August of 2008; correct?

A He is. But at this point in time, there was no production, no ongoing production, so everything was stopped.

Q And you were actually unhappy at the same time frame about the company's problems being publicly aired, weren't you?

A I don't know what you mean by that.

(Plaintiff's Exhibit No. 117 was marked for identification.)

BY MR. BLIZZARD:

Q Let me show you what I'm going to mark as Exhibit No. 117 to your deposition. And this is Document 527229.

A Uh-oh.

Q Is this top e-mail an e-mail authored by you on August the 13th of 2008?

A Yes, it is.

Q Okay. And that's the same time frame the previous exhibit, 117 was dated August 14 of 2008 from Mr. --

A I'm sorry?

Q Mr. Castellazzo's e-mail was dated August 14th, so it's in the same time frame as

his e-mail; correct? I'm not saying there's a connection between them.

A Yes. Okay.

Q It's in the same time frame, isn't it?

A Yes.

Q So your e-mail says: "This sucks." Right?

A Yes.

Q "The quotes they lifted are in every warning letter and recall press release."

A Yes.

Q And that's the totality of the e-mail; correct?

A Yes.

Q And the e-mail relates to a news article that is entitled "GMP Storm Cloud: Generic Firms May Get Further Scrutiny After Actavis Recall."

Is that the title of the article?

A Yes.

Q Do you know in what newspapers that article appeared?

A I believe it's trade industry press.

It's not regular news. I'm not sure.

Q What is it that you're referring to when you say, "This sucks"?

A It's -- I would have to read through it. Can I --

Q Sure.

A I didn't read through all of it, but I refreshed my memory enough to know that the part about it that I didn't like was that Actavis was being lumped in with Ranbaxy and other companies that had, at least in my opinion, more significant issues, particularly with Department of Justice being involved with Ranbaxy's products in India.

Q And actually Ranbaxy issues, actually there was evidence of outright fraud, wasn't there?

A Right.

Q But the actual information that was included in the quotes, as you say in your e-mail, was taken out of the warning letter and the recall press release; correct?

MR. DEAN: Objection.

Go ahead.

That's a miscategorization of that sentence.

BY MR. BLIZZARD:

Q Does the sentence say: They -- "The quotes they lifted are in every warning letter and recall press release"?

A Yes.

Q And in the second paragraph, is there a quote there that says: Actavis said August 1 that it is recalling all 65 products manufactured at the plant following an inspection that, quote, revealed operations which did not meet the FDA's or Actavis' standards for good manufacturing processes?

Did I read that correctly?

A Yes.

Q And do you agree that the inspection by FDA did reveal operations which did not meet the FDA or Actavis' standards for good manufacturing practices?

A Yes. But that is also a standard statement that is in most recall notices.

Q Well, is that something that you think the public should be entitled to know?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: I'm not sure -- the reason for the recall? Is that what you're asking me, the public should know the reason for the recall?

BY MR. BLIZZARD:

Q Yes. Yes.

A Yes, you need to state the reason for the recall.

Q Right. I guess what I'm trying to make sure is that you're not saying that telling the public that the company was not meeting good manufacturing practices sucks? You're not saying that, are you?

A No. I -- can I elaborate?

Q Sure.

A What I'm saying is that taken out of context, to take just the snippets of what happened at Actavis and try to liken it to fraud in Ranbaxy was an -- it's an unfair article.

Q Okay.

A And this article, as I said, was

trade press for the pharmaceutical industry, not a newspaper article for the public.

Q So what you're saying is Ranbaxy was intentionally trying to defraud the --

A I have no knowledge of that.

Q Okay. Well, that's what the reports that you heard?

A Exactly.

Q Okay. But you know that FDA, as we talked about earlier today, found that the quality system of Actavis was a total failure; correct?

A I also know that this investigation by the Justice Department against Ranbaxy was dropped.

Q Okay. But what happened -- wasn't there a proceeding by the Justice Department against Actavis?

A Subsequently, yes.

Q When was that?

A Discussions began with the Department of Justice in September.

Q And did you resign shortly after that proceeding was initiated?

A In November.

Q Did you resign in part because of the proceeding?

A Yes.

Q Why?

A Because the Justice Department was proceeding with a consent decree which not only named the company but also named the individuals, one of which was me. And after several rounds of discussion as to who should be and who should not be named on the document, my name was -- several of the names had been dropped, and my name was still on the consent decree.

And I had asked that it be removed, mainly because my experience in industry tells -- has -- based on other cases was that once your name is on a consent decree, it becomes part of your public record and history. And I did not really want that in my background check. It would be a limiting factor in my future employment. And even though cases have gone to trial and those cases have, I guess, exonerated the

individuals, it still sort of follows them.

So while I was more than willing to stay with the company and carry out -- because I've done so in other organizations, as we mentioned earlier with Barr, more than willing to go through the consent decree activities, I felt that I was a better use to them as a person doing the work as opposed to the person being named on the decree.

Q Was your name taken off the consent decree after you resigned?

A Yes.

Q And was that part of a condition of your resignation?

A Yes. It was the only way the name would have come off.

Q Now, before the Justice Department took action against Actavis, you said discussions started in September of 2008?

A Yes.

Q Were there additional problems that developed during the remediation effort?

MR. DEAN: Remediation of Digitek?

BY MR. BLIZZARD:

Q Were there additional problems with -- let me ask you this: Did the quality system that was in effect at Actavis, did it cover all the drugs manufactured by Actavis?

A The quality system would cover the entire facility, yes.

Q Okay. So there weren't any drugs that were excluded from the operation of the quality system; quality applied to each of the drugs; right?

A Yes.

Q So were there problems with the quality system in September of 2008?

MR. DEAN: Objection. It's vague and ambiguous. You've already established they weren't making product at that point, Ed. Could you clarify that?

(Plaintiff's Exhibit No. 118 was marked for identification.)

BY MR. BLIZZARD:

Q Let me just show you a document that's marked as Exhibit 118. This is

1267772.

Do you see the first e-mail here is from Tony Delicato to Erislandy Dorado with a carbon copy to you and Chris Young?

A Yes.

Q And it's dated September 16 of 2008; is that right?

A Yes.

Q And then the subject says: "These are just examples - not all - inclusive."

Is that what it says?

A Yes.

Q And it says: Quality unit responsibilities SOP outdated/not accurate.

Do you know what that refers to?

A There was an SOP, a standard operating procedure. And the one that was in place did not reflect what was -- what we wanted to have going forward, so it needed to be revised.

Q Then it says: Quality review board - SOP effective but no meetings held as functional areas have not had time to generate metrics.

Is that what it says?

A Yes.

Q What was your understanding of that issue?

A The quality review board is typically a management-level review that would look at trends and look at whatever the metrics were that were decided upon.

So what he's saying here is that we put the SOP in place, but we haven't had meetings because they have to still gather the metrics to do that.

Q Okay.

A These metrics here, again, in this time frame would be all of the past history.

Q There's a recall SOP update. It says: Revision in process but not ready?

A Correct.

Q Is that what that says?

And it says: The site master plans - with the exception of analytical...are the others accurate and reflect current thinking? Same for SOPs that govern EQ, PV, and CV.

What's EQ, PV, and CV?

A Equipment qualification, process validation, and cleaning validation.

Q Then it says: Complaint and APR SOP - requires revision; IP but not ready.

What's IP stand for?

A In process.

Q Then it says: Complaints - approximately 250 digoxin complaints overdue due to Class I recall - massive volume received.

Is that what that says?

A Yes.

Q Then it says: Training level of departments - at or just below 80 percent...we are working on closing gaps to get 95 percent but not there yet.

And then he says: "I could go on but you get the point."

Is that what he says?

A Uh-huh.

Q And then he says: "Please don't get me fired. We are doing the best we can under the circumstances."

A Uh-huh.
Q And then you respond to it; correct?
A Yes.
Q And what do you say?
A "Don't worry. You can stay. I'll go."
Q Were you actually contemplating that at the time?
A No. Actually, that was all in jest.
(PLAINTIFF'S Exhibit No. 119 was marked for identification.)
BY MR. BLIZZARD:
Q Finally I want to show you a document that's marked as Exhibit No. -- I'm going to mark as Exhibit No. 119. And this is 00 -- I'm sorry -- 309296.
A Yes.
Q Does this appear to be a document that's dated November 2008, "Monthly Deviations and CAPA Data"?
A Yes.
Q What does "CAPA" stand for?
A Corrective and preventive action.
Q So is this part of the corrective

action plan?

A No. CAPA is a normal, coined, sort of GMP phrase, corrective and preventive action. CAPA should be part of every quality system.

Q Okay. And this appears to be a monthly report from November; is that accurate?

A Yes.

Q If you'll go over to Page 2, November of 2008 was less than a month before you left or a month before you left?

A I'm sorry?

Q I'm sorry. Let me rephrase that.

When did you leave Actavis? When did you resign?

A November 13.

Q Did you see this plan before you resigned?

A I've never seen this.

Q Have you seen any monthly reports similar to this before you resigned?

A Similar, yes.

Q If you look at the second page, it

says: "Corrective and Preventive Actions - Little Falls."

A Uh-huh.

Q And there's a percent overdue in the middle of this. It says 67 percent; right?

A Yes.

Q So it's 67 percent of the corrective and preventive actions the company had agreed should be done for the Little Falls facility were still -- were overdue?

A No, that's not correct.

Q Explain that for me.

A This is a self-imposed activity. So what's being reflected here is out of all of the tasks that we chose to work on, based on everything that we were doing to get the site ready, to reintroduce product, there were numerous activities and there were proposed deadlines. And this is just tracking that.

So these were not commitments to FDA. That was a management reporting mechanism. And at this particular point in time, the operations had ceased. So the activities, if they were overdue, were only

preventing the company from reengaging in the manufacture of product. So it was only -- we were only holding up ourselves. All product was off the market at this point in time, and all of these activities were activities to bring product back. So if they were overdue, they were overdue.

Q It was just the company losing money?

A Precisely.

MR. BLIZZARD: Why don't we take a couple minutes. I may be finished with my questioning.

MR. DEAN: Sure.

THE VIDEOGRAPHER: We are now going off the record. This is the end of Videotape No. 3. The time is 2:17.

(Short recess.)

THE VIDEOGRAPHER: We are now back on the record. This is the beginning of Videotape No. 4. The time is 2:28.

MR. BLIZZARD: Ms. Lambridis, we're back on the record. I've looked at

my notes. I don't have any additional questions for you at this time. And I want to thank you for your time.

THE WITNESS: You're welcome.

THE VIDEOGRAPHER: Off tape, 2:28.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on tape, 2:29.

BY MR. PETTIT:

Q Good afternoon, Ms. Lambridis. I name is Jim Pettit. I'm an attorney with Locks Law Firm, and I'm going to ask you some questions on behalf of the PSC and on behalf of New Jersey plaintiffs. There may or may not be an objection to that. But, in any event, I'm going to be asking you questions on behalf of the PSC.

MR. DEAN: Before you start, let me just restate my objection. I have no objection to you asking any questions on behalf of the New Jersey state plaintiffs. The depositions were not cross-noticed. I'd like to reiterate

that. I have no objection to you asking any questions in your role as PSC.

So go ahead.

BY MR. PETTIT:

Q Those were legal objections.

Ms. Lambridis, I'm going to try very hard not to ask you questions that are the same or even similar to Mr. Blizzard's. I had a lot of questions that were similar and some of the same documents. So I'm going to be zigzagging a lot more than Mr. Blizzard was. And, also, I'm going to be using the Elmo rather than the nice digital computer projection that he used, so it's not going to be quite as smooth.

All right?

A Okay.

Q Mr. Blizzard asked you some questions about your employment, and you said you began with Actavis in September 2007. I was wondering if you could tell us the exact date.

A The 17th.

Q So you came into the Actavis company

during the FDA inspection that took place between September 5th, 2007, and September 28th, 2007; correct?

A Correct.

Q And were you involved with that in terms of physically walking around with the FDA inspectors?

A No.

Q Is there a reason that you were not? Is there a reason that you're aware of that you were not?

A There was no reason given, but I just started. I had a week of orientation. And honestly I wouldn't be able to host an inspection with no knowledge of the facility, so there was no point in my participating as far as from my own perspective.

Q When you left Actavis, which was, I think you told us, December 1st, 2008 --

A December 1st was technically the last day of employment, but I resigned on the 13th. And my last day on-site was the 17th, I believe, of November.

Q You resigned in November and left in

November?

A Correct.

Q Physically left?

A Physically left.

Q Did you have sources of income between December 1st, 2008, and when you went to Halo in May 2009?

A I had started consulting again. I had applied for unemployment and was received -- and received unemployment. And I subsequently negotiated a consent -- a consulting agreement with Actavis.

Q Have you received any income from Actavis since December 1st, 2008?

A Me personally?

Q Yes.

A As a consultant. So the consulting agreement, I believe, was signed in 2009, April, March or April of 2009. And then payments made -- are made to Framework, which is my consulting company.

Q And when was the last date that you received any income from Actavis?

A "Last" meaning most recent?

Q Yes.
A The beginning of this month. The payment is monthly.
Q And what consulting have you done in the last month for Actavis?
A The way the agreement is drawn up, it is to retain my services for -- if needed because of my involvement with all of the activities that we're discussing here.
When I left, they were still negotiating through the consent decree. They were still trying to resume manufacturing at the Totowa facility. And they did have the pending litigations which they knew they may need my help with. So I was retained as a consultant with the understanding that I would be available to them when they needed me.
Q And when you say "pending litigations" in your last answer, do you mean -- does that include personal injury Digitek litigation, or are you just talking about U.S. Government?
A I'm talking about all of it.
Q Everything.

A Uh-huh.
Q Are you invoicing in any way your time spent in preparing for this deposition?
A No.
Q How about giving the deposition?
A No.
Q I want to ask you some, I think, pretty basic questions about the three facilities in New Jersey. Okay?
A (Witness shakes head.)
Q When you have been using the term the "Little Falls facility" today, you're always talking about the Main Street facility?
A Little Falls is typically the Main Street facility.
Q And the Taft Street -- and I'm oversimplifying this -- was more packaging than actual manufacturing operations; correct?
A Yes. Taft has specifically packaging and some R&D labs.
Q So there was never any Digitek manufacturing at Taft; correct?
A As far as I know.
Q Would you or in your -- all right.

During your time period, there was never any manufacturing?

A Never any manufacturing there.

Q Was there ever any actual Digitek manufacturing production at Riverview?

A There were batches manufactured at Riverview for the purpose of getting that site approved to manufacture there subsequent to the inspection.

Q Okay. So --

A So those batches were never marketed.

Q And that's in relation to a requirement that for Digitek to be produced in a different facility, you had to go to the FDA and get certain approvals?

A Correct.

Q What is the status of the building at Little Falls on Main Street?

A As far as I'm aware now, that building is operating still, has had subsequent FDA inspections. I believe they reintroduced one product, two strengths of one product.

Q And if you went to that facility today, would there be any signs identifying it as an Actavis facility on the outside of the building?

A I haven't been there, but typically there would be.

Q When was the last time you were in that Main Street facility?

A Prior to November 13th of --

Q 2008.

A -- 2008.

Q And did the sign outside the building then say "Actavis"?

A Yes.

Q What is the status of the building on Riverview Drive? And is that in Totowa?

A Riverview Drive is in Totowa and --

Q What is the -- go ahead.

A -- I don't know the status. I believe the laboratory is still there, but I -- I don't know the current status.

Q What was the status -- when is the last time you were there? The end of 2008?

A Yes.

Q What was the status then of that building?

A For lack of a better term, I guess limbo would be the best. Because the inspection didn't result in them being able to move into that building, it was still an unknown as to whether they were going to proceed and what they were going to do.

Q Is "limbo" a religious term or a legal term? No. Just kidding.

A Business term.

Q When you were answering some questions to Mr. Blizzard, you told him -- and I'm paraphrasing. The record will speak for itself as to what you said precisely. But you said on April the 9th, 2008, you had a written commitment that there was a probable Class I Digitek recall.

Do you remember testifying about that today?

A I didn't -- I didn't say it was Class I. I had made a comment to a colleague that it looked like the Digitek was going to result in recall of that batch.

Q And was that on April the 9th, 2008?
A According to the memo that was presented, it was April 9th.
Q And does that date seem correct to you now?
A It seems, yes, factual.
Q Now, the actual letters going to Mylan that Mr. Blizzard talked to you about, that one letter that went out over your signature, do you remember that?
A Yes.
Q You said that even though that letter was dated April the 28th, you thought -- you didn't know the exact date it went out, and you thought it was a few days later; is that correct?
A Yes.
Q Do you, sitting here an hour later, do you remember when it went out precisely?
A I don't know the exact date. The letter that was in front of me today was the draft, and it didn't have a signature on it.
So in the case of the Digitek recall, we were working with a third party to

handle these recalls. So sometimes I would sign a document, and those letters didn't go out for a day or so because of the mailings. So I don't -- the day I signed it and the day it actually goes out may differ.

Q Would you think that the earliest that that April 28, 2008, letter to Mylan, that the earliest date it went from Actavis to Mylan would have been in the first week of May?

A I couldn't say.

Q If the letter were dated April the 28th, 2008, would you agree with me that the earliest it would have gone to Mylan was a few days later, according to your testimony, which would put it in the first week of May?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: I -- I don't know, but I guess that's possible.

BY MR. PETTIT:

Q Is it likely?

A I could look at the dates. I mean, if April 28th was on a Thursday and May 1st

was a Tuesday, it's possible.

MR. PETTIT: I'm going to mark this as 120.

(Plaintiff's Exhibit No. 120 was marked for identification.)

BY MR. PETTIT:

Q Ms. Lambridis, I've shown you a document which I have marked as Exhibit 120. It has Bates No. UDLL004006, and it's three pages long.

Do you see that?

A Yes.

Q Now, this is, would you agree with me, a letter that's similar to Exhibit 113 that Mr. Blizzard showed you, except that document had Xs on the sentence that says, quote: Actavis has distributed the subject lots from 3/1/06 through 4/24/08, quote/unquote.

Do you see where it says that on this exhibit?

A Yes, but that's not the only difference.

Q I'm not saying that it is.

A Yes, yes.
Q I'm saying some of the Xs have been filled in; correct?
A Uh-huh.
Q When you look at this exhibit, Plaintiff's 120, does that seem to you to be the final draft?
A When I look at this document, I can tell you that it's a copy of the draft that we at Actavis prepared and it was modified to accommodate recalls done by Mylan.
Q Does that time period seem accurate to you that recall lots went from March 1, 2006, to April 24, 2008?
A I can't say specifically to the exact dates, but that would reflect the two-year period. So when you're doing the recall, you would have to go back to -- because it was for all lots, it would be any lots within expiry. So based on the dates with the two-year expiry, that would cover all lots manufactured in that time.
Q And just so the jury knows what that technical word "expiry" means --